UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

April 1, 1998

MEMORANDUM

SUBJECT: Tetrachlorvinphos, The Revised HED Chapter of the Reregistration Eligibility Decision Document (RED), Case 0321, Chemical 083701

FROM: Kathryn Boyle, Chemist /s/
Reregistration Branch I
Health Effects Division (7509C)

THROUGH: Whang Phang, Branch Senior Scientist /s/
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TO: Arnold Layne, Chief
Reregistration Branch I
Special Review and Reregistration Division (7508W)

The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The Tetrachlorvinphos Reregistration Eligibility Decision Document (RED) was signed in 1995. Due to the enactment of the Food Quality Protection Act of 1996, the Special Review and Reregistration Division of OPP has requested that HED re-evaluate toxicology and residue chemistry data, and then perform dietary, residential, and occupational risk assessments to estimate the mitigation measures and tolerance reassessments necessary for the reregistration of tetrachlorvinphos. It should be noted that the RED declared certain uses of tetrachlorvinphos not eligible due to the Delaney Clause.

The revised Human Health Assessment for the Reregistration Eligibility Document for tetrachlorvinphos is attached. The following committees or individuals in OPP have contributed to this reassessment: Exposure SAC (review of revised occupational and residential assessments), Sid Abel (water), Kit Farwell (toxicology), David Miller (chemistry), and Hazard Identification SARC (FQPA determinations).

Actions Required:

As recommended in the 1995 Human Health Assessment, all tolerances for plant commodities MUST be revoked.

If the plant tolerances are not revoked, then the following data are required:

860.1300 Nature of the Residue - Plants
860.1340 Residue Analytical Method - Plants
860.1380 Storage Stability Data (to support the above)
860.1500 Crop Field Trials

Required Data:

Toxicology
No data gaps

Product Chemistry
UV/visible absorption for the PAI
Data to fulfill the 9/92 HCB/PCB DCI
Data to fulfill the 6/87 dioxin/dibenzofuran DCI

Residue Chemistry
Storage Stability Data - for tetrachlorvinphos and the four metabolites in animal tissues and milk to support the magnitude of the residue in animal studies

Meat, milk, poultry, and eggs - magnitude of the residue studies with cattle, poultry and swine are required. Residues studies reflecting both feed through and dermal applications are required for cattle and hogs. Only dermal studies are required for poultry.

Analytical methodologies for separate determinations for parent tetrachlorvinphos and metabolites in meat and milk

Occupational Exposure
Data for evaluating mixer/loader/applicator exposure for dusters and pellets
GLN 233 Dermal Exposure at Indoor Sites
GLN 234 Inhalation Exposure at Indoor Sites

Residential Exposure
Additional information on the amount of product used, the number of days the product is used, the number of years the product is used for all formulations

Label Amendments

A label amendment is required for the 7.76% G formulation (EPA Reg. No. 56493-35) to prohibit treatment of horses destined for slaughter. If, this label change is not made, then feed through and dermal studies are required for the horse.

When end-use product DCIs are developed (e.g., at issuance of the RED), all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) should be amended to be consistent with the basic producer labels.

TETRACHLORVINPHOS

THE REVISED HED CHAPTER

Introduction

This document superceedes the previous HED chapter signed in 1995. The requirements of the Food Quality Protection Act dictated the need for revisions.

In this document, which is for use in EPA's development of the tetrachlorvinphos Reregistration Eligibility Decision Document (RED), Health Effects Division (HED) presents the results of its risk assessment/characterization of the potential human health effects of dietary, residential and occupational exposure to tetrachlorvinphos. Included is a discussion of the available product chemistry data, toxicological studies, and residue chemistry data.

It should be emphasized that the results of the risk assessment presented in this Assessment could change as a result of additional information or new data submissions. Changes to the risk assessment could also result if changes in labeled uses are made to achieve risk reduction.

The Food Quality Protection Act (FQPA) was signed on August 3, 1996. FQPA amended both FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and FFDCA (Federal Food, Drug and Cosmetic Act). FQPA requires the Agency to consider aggregate exposure in its decision-making process for dietary (food source and drinking water), residential , and other non-occupational exposures. The tetrachlorvinphos risk assessment presented in this document is a single chemical/multi-pathway assessment. Note that under FQPA occupational exposure is prohibited from being aggregated with any other exposures for the purpose of tolerance setting.

FQPA requires that the Agency consider the cumulative effects of tetrachlorvinphos and other chemicals that have a common mechanism of toxicity. This requires that the Agency first determine that a common mechanism of toxicity exists for a group of chemicals, decides on the appropriate methodology for combining exposures, and then, after reviewing use information/patterns, determines which of the exposures/scenarios for which chemicals are to be added together, i.e. aggregate exposure does occur.) Tetrachlorvinphos is an organophosphate (OP). The Agency is in the process of ascertaining whether or not tetrachlorvinphos has a common mechanism of toxicity with other OPs. Additionally, the single chemical/multi-pathway assessments of each of the other chemicals must be completed before the Agency could perform the multi-chemical/multi-pathway assessment.

Summary of Risks

No acute dietary risk assessment was required.

No short-term or intermediate-term occupational or residential risk assessments were required.

Due to the use pattern a drinking water assessment was not required.

Chronic (non-cancer) Dietary - This assessment was performed using anticipated residues and percent livestock treated data and considering only those uses recommended through reregistration. For the U.S. population, the percent RfD occupied is 1%, for non-nursing infants 2%, for children (1 - 6 years) 3%.

Carcinogenic Dietary - For the U.S. population, for adult males, and adult females, the risks are 9.6×10^{-7}, 7.7×10^{-7}, and 7.2×10^{-7}, respectively.

Carcinogenic Occupational - For all but three scenarios, risks are less than 10^{-6} at baseline. Mixing/loading wettable powder requires used of gloves, and the use of a low pressure handwand or a backpack requires use of PPE to mitigate.

Carcinogenic Residential - Risk is dependent on the product, the amount used, and the frequency of application. For applicators, risks range from 10^{-5} to 10^{-10}. Post-application risks range from 10^{-6} to 10^{-10}.

Carcinogenic Aggregate - Dietary (food) + Residential (application and post-application) - These aggregate risks range from 10^{-5} to 10^{-7}.

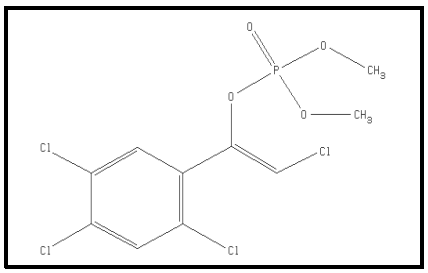
Only time-limited tolerance reassessments could be performed.

II. Science Assessment

A. Physical and Chemical Properties Assessment

1. Description of Chemical

Tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate] is a non-systemic organophosphate insecticide. It is federally registered for use as an oral larvicide for livestock and for direct treatment of beef cattle, dairy cattle (including lactating animals), horses, poultry, swine, and livestock premises. There are homeowner-use products for controlling fleas on cats and dogs, and their bedding.



Tetrachlorvinphos (beta isomer)

Empirical Formula:	$C_{10}H_9Cl_4O_4P$
Molecular Weight:	366.0
CAS Registry No.:	22248-79-9
Shaughnessy No.:	083701

Identification of Active Ingredient

Technical tetrachlorvinphos is a tan to brown crystalline solid with a melting point of 93-98° C and a bulk density of 50-55 lb/cu ft. The solubility of tetrachlorvinphos in water at 24° C is 15 ppm. Tetrachlorvinphos has limited solubility in most aromatic hydrocarbons (i.e., 40 ppm in chloroform and dichloromethane, 20 ppm in acetone, and 8 ppm in xylene at 0° C).

Manufacturing-Use Products

A search of the Reference Files System (REFS) conducted 3/16/94 for the first HED chapter identified five tetrachlorvinphos manufacturing-use products (MPs). At the time of the Tetrachlorvinphos Guidance Document (10/88), E.I. du Pont de Nemours and Company was the only producer of technical tetrachlorvinphos (99.1% T; EPA Reg. No. 352-460); this product had been registered to Shell Chemical Company under EPA Reg. No. 201-225 prior to the Guidance Document. The du Pont 99.1% T was voluntarily canceled 12/93. The Fermenta 97.3% (EPA Reg No. 56493-38) and 75% (EPA 56493-19) formulation intermediates (FIs) were also registered at the time of the Guidance Document and were formulated at that time from the du Pont technical. The three technicals (T) located in the 3/16/94 search (62725-1, 2596-131, and 56493-88) were "me too" registrations which relied on the du Pont database.

A new REFS search on 11/7/97 indicated that all Fermenta registrations have been transferred to Boehringer Ingelheim Animal Health Inc. Registration 56493-88 was cancelled on 7/19/95 for non-payment of the maintenance fee.

The products listed in Table 1 are the only MPs subject to this decision.

Table 1. Registered Tetrachlorvinphos Manufacturing-Use Products.

Formulation	EPA Reg. No.	Registrant	Date Registered
98.7% T	2596-131	Hartz Mountain Corp.	9/92
98.7% T	4691-149	Boehringer Ingelheim Animal Health Inc.	10/92
97.3% FI	4691-135		8/86
75% FI	4691-129		8/86

All tetrachlorvinphos products are subject to a 6/87 Data Call-In Notice (DCI) for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans. The Agency has determined that analysis of tetrachlorvinphos for 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD) at 0.1 ppm and 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF) at 1.0 ppb would be sufficient to fulfill the DCI requirements. However, polychlorinated dibenzo-p-dioxins and dibenzofurans are not expected to be of concern in tetrachlorvinphos products based on studies submitted for the du Pont technical in which 2,3,7,8-TCDD and 2,3,7,8-TCDF were not detected at levels above the DCI-specified screening levels.

A 9/92 DCI for analytical chemistry data on hexachlorobenzene (HCB) and pentachlorobenzene (PCB) is also in effect for technical tetrachlorvinphos. Data concerning this requirement have not been submitted; however, an acceptable protocol was submitted by du Pont prior to the voluntary cancellation of the 99.1% T. All product chemistry requirements were fulfilled for the du Pont 99.1% T prior to its 12/93 cancellation, except for those requirements specified in the 9/92 HCB/PCB DCI.

Hartz and Boehringer Ingelheim Animal Health Inc. must identify the current source of the Technical Grade Active Ingredient (TGAI). TGAI data requirements will be the responsibility of the registrant of the technical grade product.

The current status of the product chemistry data requirements for tetrachlorvinphos manufacturing-use products is presented in Table 2. Provided that the registrants resolve the issue of the use of the duPont database or submit a complete updated product chemistry data package, HED has no objections to the reregistration of tetrachlorvinphos with respect to product chemistry data requirements.

The following product chemistry database for the canceled du Pont 99.1% T (EPA Reg. No. 352-460) is presented for informational purposes only.

Table 2: Tetrachlorvinphos Product Chemistry Data Summary

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number
830.1550	Product Identity and Disclosure of Ingredients	Y	41222501 41222502
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Y	41222501 42013001
830.1670	Discussion of Formation of Impurities	Y	40491301 41222501 42013001
830.1700	Preliminary Analysis	N [b]	40924701 41222502
830.1750	Certification of Ingredient Limits	Y	41222502
830.1800	Analytical Methods to Verify the Certified Limits	Y	41222502 42013002 42275201 42679201
830.6302	Color	Y	41222503
830.6303	Physical State	Y	41222503
830.6304	Odor	Y	41222503
830.6313	Stability	Y	41222503
830.6314	Oxidizing or Reducing Action	N/A [e]	
830.6315	Flammability	N/A [f]	
830.6316	Explodability	N/A [g]	
830.6317	Storage Stability	Y	41222503 42013003 42407801
830.6319	Miscibility	N/A	
830.6320	Corrosion Characteristics	Y	41222503 42013003
830.7000	pH	Y	41222503
830.7050	UV/visible Absorption	N[h]	
830.7100	Viscosity	N/A	
830.7200	Melting Point/Melting Range	Y	41222503
830.7220	Boiling Point/Boiling Range	N/A [c]	
830.7300	Density/Relative Density/Bulk Density	Y	41222503
830.7370	Dissociation Constant in Water	N/A [d]	
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	Y	41222503
830.7840 830.7860	Solubility	Y	41222503
830.7950	Vapor Pressure	Y	41222503

a Y = Yes; N = No; N/A = Not Applicable.

b Data are satisfied for 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis and analysis for dioxins; however, data concerning the HCB/PCB Data Call-In dated 9/92 remain outstanding (CBRS Nos. 13016 and 13025, D197423 and D197977, dated 1/11/94, by S. Funk).

c Data are not required because the TGAI/MP is a solid at room temperature (CBRS No. 5315, dated 6/13/89, by J. Garbus).

d Data are not required because the TGAI/PAI is non-ionizable in aqueous solution and has no acid/base properties (CBRS No. 5315, dated 6/13/89, by J. Garbus).

e Data are not required because the MP has no significant oxidizing or reducing character (CBRS No. 5315, dated 6/13/89, by J. Garbus).

f Data are not required because the MP is not a combustible liquid (CBRS No. 5315, dated 6/13/89, by J. Garbus).

g Data are not required because the MP does not contain any potentially explosive ingredients (CBRS No. 5315, dated 6/13/89, by J. Garbus).

h The OPPTS Series 830, Product PropertiesTest Guidelines require data pertaining to UV/Visible absorption for the PAI

B. HUMAN HEALTH ASSESSMENT

1. Hazard Assessment

Toxicology data are used by HED to assess the hazards to humans and domestic animals. The data are derived from a variety of acute, subchronic, and chronic toxicity tests; developmental/reproductive tests; and tests to assess mutagenicity and pesticide metabolism. Reregistration eligibility decisions require that HED have sufficient information to select the appropriate end-points for performing a human health risk assessment. This requires a toxicological database that is not only complete, but of acceptable quality.

The toxicity database for tetrachlorvinphos is adequate and will support reregistration eligibility.

a. Acute Toxicity

Acute toxicity values and categories for tetrachlorvinphos are summarized in Table 3.

Table 3: Acute Toxicity Data

TEST/ GLN	MRID	RESULTS	CATEGORY
Oral LD50--rat/ 81-1	41222504	1480 mg/kg M; 465-965 mg/kg F	III
Dermal LD50--rabbit/ 81-2	41222505	>2 g/kg	III

TEST/ GLN	MRID	RESULTS	CATEGORY
Inhalation LC50--rat/ 81-3	00138933	>3.61 mg/L	III
Eye irritation--rabbit/ 81-4	41222506	moderate	III
Dermal irritation--rabbit/ 81-5	41222507	slight	IV
Dermal sensitization--guinea pig/ 81-6	41377902 42981001	sensitizer	--

b. Subchronic Toxicity

In a 21-day dermal toxicity study, Crl:CD BR rats were given doses of 0, 10, 100, or 1000 mg/kg/day tetrachlorvinphos which was applied 6 hours/day, 5 days/week for a total of 15 treatments over the 21 day period. The NOEL was 100 mg/kg/day for females and 1000 mg/kg/day (the high dose) for males. The LOEL was 1000 mg/kg/day for females, based on decreased plasma cholinesterase activity. No other systemic effects and no dermal effects were found (GLN 82-3; MRID 41342001).

Tetrachlorvinphos was given to Sprague Dawley rats in the diet at doses of 0, 100, 2000, or 5000 ppm (0, 4.23, 43.2, and 88.5 mg/kg/day for males; 0, 5.93, 62.7, and 125.3 mg/kg/day for females) for 13 weeks. The NOEL was 100 ppm for both sexes. The LOEL was 2000 ppm based on reduced plasma and red blood cell (RBC) cholinesterase activity in both sexes. At the highest dose, these effects were seen along with reduced brain cholinesterase activity in females. The two highest doses had reduced body weights and reduced weight gains, as well as bilateral basophilic tubules of the kidneys in males, increased fat deposition in the adrenal cortex of females, centrilobular hepatocellular hypertrophy in females and mid-dose males, and higher adjusted adrenal weights in females. In both sexes at the two highest doses there were thyroid follicular cell hypertrophy and higher adjusted liver weights (GLN 82-1; MRID 43371201).

c. Chronic Toxicity

In a one-year oral study, tetrachlorvinphos was given to beagle dogs by capsule at doses of

0, 6.25, 500, or 1000 mg/kg/day. The systemic NOEL was 6.25 mg/kg/day. The systemic LOEL was 500 mg/kg/day, based on decreased RBC counts, hemoglobin, hematocrit, and urine specific gravity. There were also increased mean corpuscular volume, alkaline phosphatase, kidney weights and liver weights. At 1000 mg/kg/day, females showed increased white blood cell (WBC) count and males showed increased prostate weight as well as decreased cholesterol. The plasma cholinesterase inhibition NOEL in both sexes was 6.25 mg/kg/day and the LOEL was 500 mg/kg/day (GLN 83-1; MRID 42679401).

In a two-year oral toxicity study, beagle dogs were given dietary doses of 0, 5, 25, 125, or 2000 ppm (0, 0.13, 0.63, 3.13, and 50 mg/kg/day, respectively). The NOEL was 3.13 mg/kg/day. The LOEL was 50 mg/kg/day, based on decreased plasma cholinesterase activity and increased relative liver and kidney weights
(GLN 83-1; MRID 00077819).

Tetrachlorvinphos was given to Porton rats at dietary levels of 0, 5, 25, 125, or 2000 ppm (0, 0.25, 1.25, 6.25, and 100 mg/kg/day, respectively) for two years. The NOEL was 1.25 mg/kg/day. The LOEL was 6.25 mg/kg/day, based on increased liver weights in females. At the highest dose, there were lower body weight, lower food intake, decreased plasma cholinesterase activity in males, decreased RBC counts and plasma cholinesterase activity in females, decreased serum total protein, decreased serum urea, decreased male kidney weights, increased male thyroid weights, and increased female liver weight (GLN 83-1; MRID 00112525).

A two year study with Sprague Dawley rats used doses of 0, 100, 1000, or 2000 ppm (0, 4.23, 43.2, and 88.5 mg/kg/day for males; 0, 5.93, 62.7, and 125.3 mg/kg/day for females) tetrachlorvinphos in the feed. The NOEL for systemic toxicity was 4.23 mg/kg/day. The LOEL was 43.2 mg/kg/day based on histological changes in liver and adrenal glands in both sexes, reduced female weight gains, and depression of plasma cholinesterase in females. High dose females also had elevated cholesterol levels. At termination, there were more thyroid C-cell adenomas for male rats in the high dose than in the controls, but this was not statistically significant (GLN 83-1, 83-2; MRID 42980901).

d. Carcinogenicity

The National Cancer Institute sponsored a carcinogenicity study in Osborne-Mendel rats. The doses were 0, 4250, or 8500 ppm, given in the diet for 80 weeks, followed by 31 weeks observation. Increased incidences of adrenal cortical adenomas and thyroid C-cell adenomas were found in dosed female rats. High incidences of thyroid C-cell hyperplasia in both sexes further indicated an effect on the thyroid (MRID 00117443).

B6C3F1 mice were fed diets containing 0, 17.5, 64, 320, 1600, 8000, or 16000 ppm tetrachlorvinphos for two years in a carcinogenicity study. For systemic toxicity, the NOEL was 1600 ppm (240 mg/kg/day) and the LOEL was 8000 ppm (1200 mg/kg/day), based on decreased weight gain. In female mice, there were statistically significant increased incidences of hepatocellular carcinoma at 8000 and 16000 ppm, of combined adenoma/carcinoma at the three

highest doses, and of adenomas at the highest dose. In male mice, there were statistically significant increases in combined hepatocellular adenoma and carcinoma incidences at the highest dose, and in kidney adenoma, carcinoma, and combined adenoma/carcinoma incidences at the highest dose (GLN 83-2; MRID 00126039).

The National Cancer Institute reported a carcinogenicity study in B6C3F1 mice. Tetrachlorvinphos was given in the feed at doses of 0, 8000, or 16000 ppm for 80 weeks, followed by 12 weeks observation. Increased incidences of hepatocellular carcinomas and granulomatous lesions of the liver were found in the dosed mice (GLN 83-2; MRID 00117443).

e. Developmental Toxicity

Developmental studies are designed to identify possible adverse effects on the developing organism which may result from the mother's exposure to the pesticide during pre-natal development.

In a developmental toxicity study, pregnant Sprague-Dawley rats were given oral doses of tetrachlorvinphos in 0.5% aqueous methylcellulose at 0, 75, 150, or 300 mg/kg/day during gestation days 6 through 15. For maternal toxicity, the NOEL was 75 mg/kg/day and the LOEL was 150 mg/kg/day based on decreased body weight gain. For developmental toxicity, the NOEL was 300 mg/kg/day (HDT); a LOEL was not established. There was no evidence of teratogenicity (MRID Nos. 40152701 and 42520101).

New Zealand white rabbits were used in a developmental toxicity study. Doses of 0, 150, 375, or 750 mg/kg/day were given by gavage on gestation days 6-19. The maternal toxicity NOEL was 375 mg/kg/day. The maternal LOEL was 750 mg/kg/day, based on mortality, abortions, and red vaginal fluid. The developmental NOEL was 375 mg/kg/day. The developmental LOEL was 750 mg/kg/day, based on an increase in early resorptions/dam with a corresponding increase in post implantation loss and a decrease in live fetuses/dam. (GLN 83-3; MRID 00127831).

f. Reproductive Toxicity

The reproduction study is designed to provide general information concerning the effects of a test substance on mating behavior, conception, parturition, lactation, weaning, and growth and development of the offspring.

In a two-generation reproductive toxicity study, Sprague Dawley rats were given 0, 100, 500, or 2000 ppm (0, 5, 25, or 100 mg/kg/day, respectively) tetrachlorvinphos in their diets for two successive generations. There was no increased sensitivity of pups over the adults. The NOEL for parental systemic toxicity was 25 mg/kg/day. The LOEL was 100 mg/kg/day based on decreased body weight gains in males in the F_0 generation, and in both sexes in the F_1 generation as well as increased adrenal gland weights in F_0 females. The NOEL for reproductive effects was 100 mg/kg/day, the HDT. A LOEL was not established. (GLN 83-4; MRID 42054301).

A three-generation reproductive toxicity study was conducted in rats using dietary doses of 0, 100, 330, or 1000 ppm (0, 5, 16.5, and 50 mg/kg/day, respectively). The NOEL for the study was 330 ppm. The LOEL was 1000 ppm, based on an increase in liver size in the F_3 generation weanlings. However, no effects were noted microscopically in the livers or any of the organs examined. No effect on fertility (number or size of litters) was noted (GLN 83-4; MRID 00077802).

g. Mutagenicity

An Ames test in Salmonella typhimurium found no mutagenic effect in strains TA98, TA100, TA1535, TA1537, and TA1538, at dose levels of 66.7, 100, 333, 667, 1000, or 3300 ug/plate with activation, or at dose levels of 10, 33.3, 66.7, 100, 333, or 667 ug/plate without activation (MRID 41222508).

A test for chromosomal aberration was conducted in Chinese hamster ovary cells. It was concluded that tetrachlorvinphos was positive for inducing chromosomal aberrations at 59.9, 79.8, and 99.8 ug/mL (but not at 29.9 or 44.9 ug/mL) in the absence of metabolic activation, but that tetrachlorvinphos was negative for inducing chromosomal aberrations at 12.5, 25, 37.6, or 75.1 ug/mL in the presence of rat S9/metabolic activation. (MRID 41312901).

In another study, cultures of rat hepatocytes were dosed with 5, 7.5, 10, 15, 20, 23, 25, 27, 30, 35, or 40 ug/mL of tetrachlorvinphos. Concentrations of 35 and 40 ug/mL were lethal. Only the cultures exposed to 10, 15, 20, 23, 25, 27, or 30 ug/mL were analyzed for evidence of unscheduled DNA synthesis (UDS). Results were negative. (MRID 42156401). (These studies fulfill GLNs 84.)

h. Metabolism

Radiolabelled tetrachlorvinphos was given orally to CD rats as a single low dose (5 mg/kg), as a single high dose (250 mg/kg), and in a series of doses (5 mg/kg). It was almost completely metabolized and most of the label was excreted in urine (46-60%) and feces (38-56%) within 48 hours of dosing. Only minor amounts were found in the tissues. Very little unmetabolized parent compound was recovered. The metabolic processes produced a number of different metabolites which were not all identified. The major metabolite observed in feces was trichlorophenylethanol with females eliminating more of this metabolite (18 - 34% total administered ^{14}C) than males (13 - 23%) at all 3 dosing levels. Trichlorophenylethandiol was also found in feces ranging from 4 - 7 % in males and 3 - 6 % in females. A major metabolite in urine, trichloromandelic acid, was excreted in males at 19 - 26% but only 10 - 12% in females. At the high dose females (25%) excreted more desmethyl tetrachlorvinphos than males (11%). However, there was essentially no difference for the low dose group with males (8%) and females (7%). (GLN 85-1; MRID 41988401).

i. Neurotoxicity

In an acute delayed neurotoxicity study, no clinical signs of neurotoxicity or neuropathology were seen in hens following two single oral doses of tetrachlorvinphos at 2500 mg/kg, 21 days apart (cumulative dose, 5000 mg/kg). It was noted that this study did not assess the potential of tetrachlorvinphos to inhibit neurotoxic esterase (NTE) in hens. (MRID No.41905901).

In an acute neurotoxicity study, no treatment-related pathological lesions were seen in the central or peripheral nervous system following single oral doses at 0, 65. 325 or 650 mg/kg to female Sprague-Dawley rats. For neurotoxicity, the NOEL was 65 mg/kg and the LOEL was 325 mg/kg based on transient clinical signs characteristic of cholinesterase inhibition (MRID No.42912501).

In a subchronic neurotoxicity study, Sprague-Dawley rats received dietary administration of Tetrachlorvinphos at 0, 200, 1000 or 5000 ppm (0, 10, 50, or 250 mg/kg/day, respectively) for 90-days. There was no evidence of neurotoxicity or neuropathological lesions in the central or peripheral nervous system. Cholinesterase activity was not measured. The NOEL was 250 mg/kg/day (HDT); a LOEL was not established (MRID No. 43294101).

There are sufficient data available to adequately assess the potential for toxicity to young animals following pre-and/or post-natal exposure to tetrachlorvinphos. These include acceptable developmental toxicity studies in rats and rabbits as well as a two-generation reproduction study in rats. In addition, no treatment-related neuropathology was seen in studies conducted in hens or rats (acute and subchronic). Therefore, based upon a weight-of-the-evidence consideration of the data base, the Committee determined that a developmental neurotoxicity study in rats is not required.

j. Domestic Animal Safety

Domestic animal safety tests for pets are generally conducted when cats, dogs, or other domestic animals will be exposed to a given pesticide through direct application for pest control or to support specific label claims for products used on pets. One cat and two dog studies were performed using formulated tetrachlorvinphos products to check for cholinesterase inhibition.

A 1987 dog study was performed using female beagles that wore collars impregnated with 14.5% technical tetrachlorvinphos. The dogs were divided into three groups - control (placebo collar), 1 collar group (recommended usage), and 2 collar group (2x recommended usage). Collars were kept on during pregnancy, parturition, and nursing. Collars identical to the mothers' were placed on the puppies at 4 weeks old.

The greatest mean measured plasma cholinesterase (ChE) inhibition (about 20-30%, which was statistically significant) occurred 12 days after these collars were applied. There was no evidence of any significant plasma ChE inhibition in the mothers or of any red blood cell (RBC) ChE inhibition in either the mothers or puppies. There were no significant dose-related differences in weight gains between the three groups of puppies, particularly when sex ratio differences between the groups were taken into consideration. (This study was undertaken to

satisfy labeling requirements; MRID 40436601)

The second dog study was performed using a formulated dip product (3.1% technical tetrachlorvinphos) applied with a sponge. Each group was composed of 6 dogs ranging in age from 2 to 12 years. Group I was sponged with water (control). Group II was sponged with a mixture of 2 oz. product/1 gallon water (1x label specified use dilution) Group III was sponged with a mixture of 8 oz. product/1 gallon water (4x group). Blood was taken from each animal on days -5, 0 (before treatment), 2, 7, and 14. There was no evidence of any statistically significant reduction in RBC and/or plasma ChE activity in any group. (GLN 86-1; MRID 41810102).

The cat study was organized in a manner identical to the second dog study. Groups I, II, and III were the same, with each group composed of 6 cats ranging in age from 3 to 8 years. Blood was taken from each animal on the same days. The results were consistent in that there was no evidence of any statistically significant reduction in RBC and/or plasma ChE activity in any group. (GLN 86-1; MRID 41810101)

2. Dose Response Section

a. FQPA Considerations

On September 23, 1997, the Health Effects Division's Hazard Identification Assessment Review Committee met to evaluate the toxicology data base of tetrachlorvinphos with special reference to the reproductive, developmental and neurotoxicity data. These data were re-reviewed specifically to address the sensitivity of infants and children from exposure to tetrachlorvinphos as required by the Food Quality Protection Act (FQPA) of 1996. The FQPA requirement was not addressed in the 1995 Reregistration Eligibility Decision Document.

Cholinesterase activity was not measured in the adults and offspring in the developmental toxicity studies or in the reproduction study. Therefore, no comparisons could be made for this endpoint between adults and offspring.

For chronic dietary risk assessments, the Committee determined that the **10 x** factor to account for enhanced sensitivity of infants and children **(as required by FQPA**) **should be removed. The present UF of 100 is adequate.** A UF of 100 is adequate to ensure the protection of this population from exposure to tetrachlorvinphos because there was no indication of increased sensitivity to young animals following pre-and/or post-natal exposure: (1) developmental toxicity studies showed no increased sensitivity of fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, and (2) a 2-generation reproduction toxicity study in rats showed no increased sensitivity of pups as compared to adults.

b. Reference Dose

A Reference Dose (RfD) represents the quantity of a substance which if absorbed on a daily

basis over a lifetime, is not expected to pose significant risk of adverse health effects.

On 5/5/94 the HED RfD Committee met and selected an RfD of 0.04 mg/kg body weight/day, based on a No Observed Effect Level (NOEL), from a 2-year feeding study in rats, of 4.23 mg/kg bwt/day in a chronic rat feeding study. (Liver histological changes and adrenal changes were observed at 43.2 mg/kg/day in male rats.) An uncertainty factor of 100 (10 for inter-species extrapolation and 10 for intra-species variability) was determined to be adequate to ensure the protection of infants and children from exposure to tetrachlorvinphos.

c. Carcinogenicity

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased tumor incidence is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship.

On 10/22/87 the HED Cancer Peer Review Committee classified tetrachlorvinphos as a Group C, possible human carcinogen, based on statistically significant increases in combined hepatocellular ademona/carcinomas (primarily carcinomas) in the female B6C3F1 mouse, suggestive evidence of thyroid c-cell adenomas, and adrenal pheochromocytomas in the rat as well as mutagenicity concerns (MRID 126039). A cancer potency factor (Q_1^*) of 1.83×10^{-3} $(mg/kg/day)^{-1}$ was estimated using the Weibull 83 time-to-tumor model. A 3/4's scaling factor was used to convert from mouse to human equivalents.

d. Assessment of Reproductive/Developmental Toxicity

The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity of young rats or rabbits following pre-or postnatal exposure to tetrachlorvinphos. Comparable NOELs were established for adults and offspring. Tetrachlorvinphos was not referred to the developmental/reproductive SARC.

e. Dermal Absorption Factor

A study was conducted with male CD rats using doses of 0.01, 0.1, 1 or 5 mg/cm^2 radiolableled tetrachlorvinphos, with some of each dose group sacrificed at 0.5, 1, 2, 4, or 10 hours. Additionally, there was a group of animals, sacrificed at 72 hours, in which the skin was washed at 10 hours. The area of the dermal application was washed to recover unabsorbed tetrachlorvinphos. Then, the skin, urine, feces, and carcass were analyzed for percent of total tetrachlorvinphos applied. For the group sacrificed at 10 hours, 84 % of the total tetrachlorvinphos applied (0.1 mg/cm^2) was recovered in the wash, and 9.57 % was in the skin, urine, feces, and carcass. The percent absorption increased with duration of exposure and generally decreased with increasing dose. The actual quantity of tetrachlorvinphos absorbed increased with increasing dose (GLN 85-2; MRID 42111501).

f. Toxicological Endpoints of Concern for Use in Human Risk Assessment

The toxicological effects of a pesticide can vary with different exposure durations. HED considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include "acute", "short-term", "intermediate term", and "chronic" risks. These assessments are defined as follows:

> Acute risk results from a one day or single event consumption of food and water, and reflects toxicity which could be expressed following oral exposure to the pesticide residues. High-end exposure to food and water residues are assumed.
>
> Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from occupational pesticide applications. Since enaction of FQPA, this assessment has been expanded. The assessment will be performed when there are primary dermal and inhalation exposures that result from residential or occupational exposures lasting from 1-7 days. However, the analysis for residential exposures will now address both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In a short term assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other assumptions built into the assessment assure adequate protection of public health.
>
> Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.
>
> Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

HED's Toxicity Endpoint Selection Committee met on 8/19/94 to select the endpoints for use in the tetrachlorvinphos risk assessment. The selection of these endpoints was later reconfirmed by the Hazard-Identification SARC on 9/27/97.

Acute Dietary Assessment:

As part of the dose-response assessment, the Agency’s toxicologists review the available database to determine the endpoints of concern. For tetrachlorvinphos there is no concern for an acute dietary assessment since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route. Therefore, this assessment for

a one day high-end dietary exposure is not required.

Chronic (non-cancer) Dietary:

The RfD is the traditionally selected endpoint for chronic dietary risk. As previously discussed, the RfD for tetrachlorvinphos was determined to be 0.04 mg/kg/day. Generally, the total chronic dietary assessment would consider both food and water; however, there is no exposure to tetrachlorvinphos from agricultural run-off. Therefore, there is no water exposure number to aggregate for the purposes of performing a chronic aggregate assessment. There is no chronic residential assessment to aggregate with the chronic dietary assessment. A percent RfD of less than 100 is considered protective.

Carcinogenic Dietary:

As previously discussed, the Q_1^* for tetrachlorvinphos was determined to be 1.83×10^{-3} $(mg/kg/day)^{-1}$. Generally, the total carcinogenic dietary assessment would consider both food and water; however, there is no exposure to tetrachlorvinphos from agricultural run-off. Therefore, there is no water exposure number to aggregate for the purposes of performing an aggregate carcinogenic assessment. Since a linear low dose approach was determined to be appropriate for tetrachlorvinphos, all residential exposures will be aggregated with the carcinogenic dietary assessment. A risk of less than 1×10^{-6} is considered protective for dietary exposure.

Short-Term (1 - 7 days) or Intermediate-Term (1 week to several months) Occupational or Residential Risk Assessment:

As part of the hazard assessment process, the Agency's toxicologists review the available toxicological database to determine the endpoints of concern. For tetrachlorvinphos the Agency does not have a concern for a short-term or intermediate-term occupational or residential risk assessment since the available data does not indicate any evidence of significant toxicity by the dermal or inhalation routes. Therefore, a short-term or intermediate-term occupational or residential risk assessment was not required.

Chronic (non-cancer) (several months to lifetime) Occupational or Residential Risk Assessment:

During the exposure assessment process, the exposures which would result from the use of tetrachlorvinphos were determined to be of an intermittent nature. The frequency and duration of these exposures (once a week or every 10 days) do not exhibit a chronic exposure pattern, since the exposure peaks and declines. The exposures do not occur often enough to be considered a chronic exposure, i.e. a continuous exposure that occurs for at least several months. Therefore, performing a chronic occupational or residential assessment is not appropriate.

Carcinogenic Occupational or Residential Risk Assessment:

As previously discussed, the Q_1^* for tetrachlorvinphos was determined to be 1.83×10^{-3}

$(mg/kg/day)^{-1}$. Since a linear low dose approach was recommended the assumption is made that any exposure to tetrachlorvinphos during a 70 year lifetime leads to an increase in the carcinogenic risk linearly proportional to the exposure level, regardless of the pattern (frequency and level) of dosing. Therefore, carcinogenic occupational and residential assessments are appropriate. Since the Q_1^* is derived from an oral study, the dermal absorption factor of 9.57% will be used. A risk within the ranges of 10^{-5} to 10^{-6} (or lower) is considered appropriate for adult workers. Note that all residential exposures will be aggregated with the carcinogenic dietary assessment. A risk of less than 1×10^{-6} is considered protective for aggregate exposure.

Table 4: Summary of Toxicological Endpoints for Tetrachlorvinphos

Exposure Duration	Exposure Route	Endpoint
Acute	---	not required
Chronic (non-cancer)	Dietary (food only)	RfD = 0.04 mg/kg/day
Carcinogenic (adult only)	Dietary (food only)	$Q_1^* = 1.83 \times 10^{-3}$
Short-Term Occupational or Residential	---	not required
Intermediate-Term Occupational or Residential	---	not required
Chronic Occupational or Residential	---	not required
Carcinogenic Occupational and Residential (adult only)	Dermal Inhalation (occupational only)	dermal absorption factor = 9.57% $Q_1^* =$ 1.83×10^{-3} $(mg/kg/day)^{-1}$

2. Dietary Exposure Risk Assessment

a. Dietary (Food Source) Exposure

The residue chemistry database includes information on the pesticide residues found in plants and animals, the levels of the detected pesticide residues, and a description of the analytical methods used. Residue chemistry data are used by HED to determine the residues of concern and to establish tolerances in food and feed. Tolerances are pesticide residue levels that should not be exceeded in or on a raw agricultural commodity in the channels of interstate commerce when the pesticide is applied according to label directions.

The residue chemistry database for tetrachlorvinphos is adequate and will support reregistration eligibility, provided the necessary label changes are made.

OPPTS 860.1200: Directions for use

A REFS search conducted on 11/7/97 identified a total of 107 products containing tetrachlorvinphos. Some of these end-use products (EPs) are used on animals that will be used for human consumption. These products are marketed in the following formulations: dust, emulsifiable concentrates, pelleted/tableted, granular, and wettable powder.

OPPTS 860.1300: Nature of the Residue

Plants

There are established tetrachlorvinphos tolerances on the following crops: alfalfa, apples, peaches, pears, tomatoes, field corn, sweet corn, and cranberries. However, no tetrachlorvinphos end-use products are federally registered for use on any plant commodities. All uses on food or feed commodities were voluntarily cancelled in 1987. These existing tolerances should be revoked. Provided the existing tolerances on crops are revoked, no plant metabolism data are required.

Livestock

The qualitative nature of the residue in ruminants following oral dosing is adequately understood. In a goat metabolism study the major metabolites identified were free 1-(2,4,5-trichlorophenyl)ethanol, conjugated 1-(2,4,5-trichlorophenyl)ethanol, and 2,4,5-trichloroacetophenone. The proposed metabolic pathway in ruminants following oral administration involves conversion of tetrachlorvinphos to trichlorophenylethanol, which is conjugated to glucuronide or further metabolized to trichloroacetophenone.

The qualitative nature of the residue in ruminants following dermal application is adequately understood. The major residues identified were the parent tetrachlorvinphos, free 1-(2,4,5-trichlorophenyl)-ethanol, conjugated 1-(2,4,5-trichlorophenyl)ethanol, and 2,4,5-trichloroacetophenone.

Tetrachlorvinphos is poorly absorbed through the skin, and most residues adjacent to the application site were not metabolized. Residues that entered the general circulation were extensively metabolized in tissues distal to the application site. In the proposed metabolic pathway in ruminants following dermal application, tetrachlorvinphos is metabolized to either 1-(2,4,5-trichlorophenyl)ethanol, which is conjugated to glucuronic acid, or to 2,4,5-trichloroacetophenone, which is converted to 2,4,5-trichlorobenzoic acid.

The qualitative nature of the residue in poultry following dermal application is adequately understood. The major residues identified were the parent tetrachlorvinphos, des-O-methyl

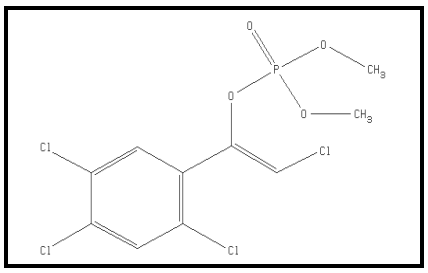
tetrachlorvinphos, free 1-(2,4,5-trichlorophenyl)-ethanol, and 1-(2,4,5-trichlorophenyl)-ethanediol. The metabolite 2,4,5-trichloroacetophenone was a minor metabolite.

Tetrachlorvinphos is poorly absorbed through the skin, and most residues adjacent to the application site were either not metabolized or were demethylated to des-O-methyl tetrachlorvinphos. Residues that entered the general circulation were extensively metabolized in tissues distal to the application site. The proposed metabolic pathway in poultry following dermal application is similar to that of ruminants except that 1-(2,4,5-trichlorophenyl)ethanol is not conjugated, but may be metabolized to the mandelic acid and benzoic acid derivatives via trichlorophenylethanediol and 2,4,5-trichloroacetophenone.

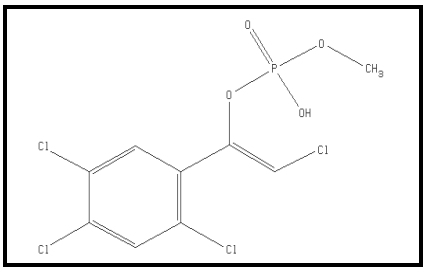
The metabolism of tetrachlorvinphos in ruminants and poultry differs. The metabolites des-O-methyl tetrachlorvinphos and 1-(2,4,5-trichlorophenyl)ethanediol are found only in hens, and the metabolite 1-(2,4,5-trichlorophenyl)ethanol is found only in goats (following both oral and dermal administration). The difference in metabolic profiles between goats and swine, both mammals, would be expected to be less significant than the difference between goat and hens. Therefore, the requirements for swine metabolism studies have been waived, provided that a magnitude of the residue study with swine is conducted including analysis of all residues of concern.

The HED Metabolism Committee has determined that the residues of concern are tetrachlorvinphos, des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)ethanediol. (See Figure A)

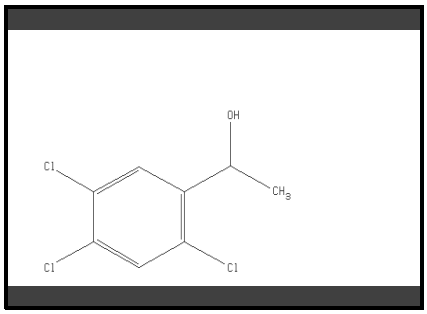
Figure A. The Chemical Structures of Tetrachlorvinphos and the Metabolites of Concern.



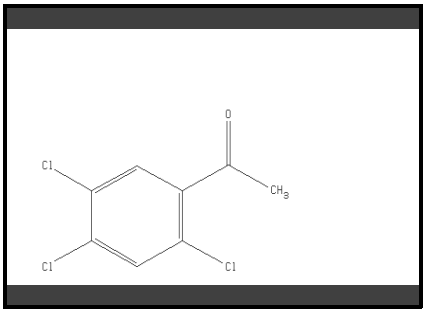
Tetrachlorvinphos (beta isomer)



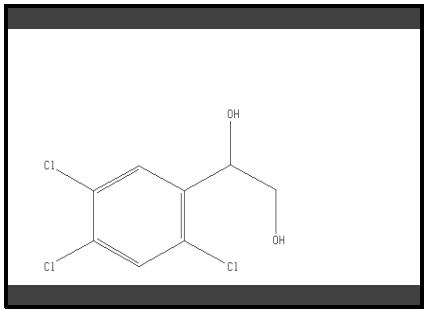
Des-O-methyl tetrachlorvinphos



1-(2,4,5- Trichlorophenyl)-ethanol



2,4,5-Trichloroacetophenone



1-(2,4,5-Trichlorophenyl)-ethanediol

OPPTS 860.1340: Residue Analytical Methods

A gas liquid chromatography (GLC) method for the determination of tetrachlorovinphos *per se* in animal commodities is described in the Pesticide Analytical Method (PAM), VOL II, as Method I. Methodology to detect and quantitate the four tetrachlorvinphos metabolites do not currently exist. Therefore, new or revised methods should be developed for tolerance enforcement and data collection purposes. The enforcement method may determine residues of the parent and four metabolites individually, or may convert all residues, including the parent, to a common moiety, as long as the parent is also determined individually. The purpose of the requirement for individual determination of residues of tetrachlorvinphos is to allow separate risk assessments for cholinesterase inhibition (involving parent only) and carcinogenicity (involving parent and four metabolites).

No tetrachlorvinphos end-use products are federally registered for use on any plant commodity. Provided existing tolerances on crops are revoked, methods for analysis of tetrachlorvinphos residues in plants are not required.

OPPTS 860.1360: MultiResidue Method

No data pertaining to the behavior of tetrachlorvinphos using FDA's multiresidue protocols

have been submitted. Samples from the animal metabolism studies should be analyzed by FDA multiresidue protocols A, B, D, and E to ascertain if the methods are capable of accurately quantifying all residues of concern. The FDA PESTDATA database dated 8/93 (PAM Vol. I, Appendix II) indicates that tetrachlorvinphos is completely recovered (>80%) using FDA multiresidue method protocol D (Section 232.4) but is not recovered using protocol E (Sections 211.1/231.1 and 212.1/232.1, fatty and nonfatty matrices).

OPPTS 860.1380: Storage Stability Data

All data requirements pertaining to storage stability have been evaluated and deemed adequate, except that additional storage stability data are required for tetrachlorvinphos and its four metabolites of concern in animal tissues and milk to support the required magnitude of the residue in animal studies. Storage stability studies have been conducted using fortified samples of milk and animal tissues. Residues of the tetrachlorvinphos *per se* are stable for 25 days at 0° C in milk, for 31 days at 0° C in milk fat, for 3 days at room temperature in muscle, for 4 days at room temperature in kidney, for 5 days at room temperature in liver, and for 11 days at room temperature in fat.

OPPTS 860.1400: Water, Fish, Irrigated Crops

Tetrachlorvinphos is not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

OPPTS 860.1460: Food Handling

Tetrachlorvinphos is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

OPPTS 860.1500 Crop Field Trials

No tetrachlorvinphos end-use products are federally registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no field residue data are required.

OPPTS 860.1520: Processed Food/Feed

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no processing data are required.

OPPTS 860,1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Ruminant, swine, and poultry magnitude of the residue studies have recently been reevaluated and found to be inadequate because none of the studies reflected dosing rates

representing the maximum expected combined exposures and did not contain data for all residues of concern. Therefore, new magnitude of the residue studies with cattle, poultry, and swine are required. Since the precise metabolism in swine is not understood, and because a magnitude of the residue study is conducted over a longer term, all residues of concern must be analyzed. The studies should reflect both the feed through and dermal applications.

No residue data are required for horses provided that all applicable labels prohibit treatment of horses destined for slaughter. The label for the 7.76% G oral larvacide formulation (EPA. Reg. No. 56493-35) should be amended to prohibit treatment of horses destined for slaughter. Otherwise, feed through and dermal studies are required for the horse.

OPPTS 860.1520: Crop Field Trials

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no confined or field rotational crop studies are required.

Tolerance Reassessment Summary

A feed additive regulation has been established for tetrachlorvinphos for use as an additive in the feed of beef cattle, dairy cattle, horses, and swine at the rates of 0.00015 lb per 100 lb body weight per day for cattle and horses, and 0.00011 lb per 100 lb of body weight per day for swine (40 CFR §186.950). Note that 40 CFR §180.950 should be deleted since time-limited tolerances for meat, milk, poultry, and eggs will be established.

The chemical name of tetrachlorvinphos as specified in 40 CFR §180.252 and §186.950, "2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate", should be replaced with "(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate".

Tolerances Listed Under 40 CFR §180.252

Currently, the tolerances specified for the raw agricultural commodities (RACs) listed in 40 CFR §180.252 are expressed in terms of residues of tetrachlorvinphos *per se*. HED's Metabolism Committee concluded that the tetrachlorvinphos metabolites des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichloro-phenylethanediol are of toxicological concern and should be regulated. The tolerance definition should therefore be revised to include the residues of these four metabolites of tetrachlorvinphos.

Currently, there are not any registered plant uses of tetrachlorvinphos. All plant uses were canceled in 1987. The established tolerances for alfalfa; apples; cherries; field corn fodder and forage; fresh corn (K+CWHR); corn grain; pop corn fodder and forage; sweet corn (K+CWHR); sweet corn fodder and forage; cranberries; peaches; pears; and tomatoes should be revoked since there are no registered uses of tetrachlorvinphos on any plant commodities.

HED is unable at this time to provide recommendations for permanent tolerance levels for tetrachlorvinphos in ruminant, swine, or poultry commodities since the required feeding studies have not yet been submitted. Based on the results of upgraded ruminant metabolism studies, HED can develop estimates of tolerances for tetrachlorvinphos in ruminant and swine commodities (except horses). Based on the results of upgraded poultry metabolism studies, HED can develop estimates of tolerances for tetrachlorvinphos in poultry commodities. It is recommended that these tolerances be time-limited for a period of no more than 18 months. This will permit adequate time for the registrant to submit the required feeding/dermal application studies.

Table 5: Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Time-Limited Tolerance[a] Reassessment (ppm)	Comment
Tolerances listed under 40 CFR §180.252			
Alfalfa	110.0	Revoke	No registered uses exist.
Apples	10.0	Revoke	
Cattle, kidney	None	1	Additional data are required. New magnitude of the residue studies with cattle are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern.
Cattle, liver	None	0.5	
Cattle, fat	1.5	0.2	
Cattle, meat	None	2	
Cattle, mbyp	None	1	
Cherries	10.0	Revoke	No registered uses exist.
Corn, field, fodder	110.0	Revoke	
Corn, field, forage	110.0	Revoke	
Corn, fresh (K+CWHR)	10.0	Revoke	
Corn, grain	10.0	Revoke	
Corn, pop, fodder	110.0	Revoke	
Corn, pop, forage	110.0	Revoke	
Corn, sweet, (K+CWHR)	10.0	Revoke	
Corn, sweet, fodder	110.0	Revoke	
Corn, sweet, forage	110.0	Revoke	
Cranberries	10.0	Revoke	

Eggs	0.1	0.2	Additional data are required. New magnitude of the residue studies with cattle, poultry and hogs are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern.
Goats, liver	None	0.5	
Goats, kidney	None	1	
Goats, fat	0.5	0.2	
Goat, meat	None	2	
Goat, mbyp	None	1	
Hogs, fat	1.5	0.2	
Hog, meat	None	2	
Hog, mbyp	None	1	
Hog, liver	None	0.5	
Hog, kidney	None	1	
Horses, fat	0.5	Revoke	No additional data required for horses provided all applicable labels prohibit treatment of horses destined for slaughter.
Horses, meat	None	Revoke	
Horses, mbyp	None	Revoke	
Milk, fat	0.5 (N) [b]	0.05	Correct commodity definition is milk
Peaches	0.1	Revoke	No registered uses exist.
Pears	10.0	Revoke	
Poultry, fat	0.75	7	Additional data are required. New magnitude of the residue studies with poultry are required because submitted studies do not contain data for all residues of concern.
Poultry, meat	None	3	
Poultry, liver	None	2	
Poultry, mbyp	None	2	
Sheep, fat	0.5	7	
Sheep, liver	None	0.5	
Sheep, kidney	None	1	
Sheep, meat	None	3	
Sheep, mbyp	None	1	
Tomatoes	5.0	Revoke	No registered uses exist.

[a] Permanent tolerance(s) cannot be made at this time because additional data are required.

For ruminant and swine commodities:

- for liver, 0.5 ppm (of which no more than 0.05 is tetrachlorvinphos per se)
- for kidney, 1ppm (of which no more than 0.05 is tetrachlorvinphos per se)
- for muscle, 2 ppm (of which no more than 2 is tetrachlorvinphos per se)
- for fat, 0.2 ppm (of which no more than 0.1 is tetrachlorvinphos per se)
- for milk, 0.05 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

For poultry commodities:

- for liver, 2 ppm (of which no more than 0.05 is tetrachlorvinphos per se)
- for muscle, 3 ppm (of which no more than 3 is tetrachlorvinphos per se)
- for fat, 7 ppm (of which no more than 7 is tetrachlorvinphos per se)
- for eggs, 0.2 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

[b] The (N) notation (designating negligible residues in whole milk) should be deleted.

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of tetrachlorvinphos. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

Anticipated Residues (ARs)

Due to the inadequate studies for magnitude of the residue in meat/milk/poultry/eggs, available residue data are insufficient to assess the established tolerances for residues of tetrachlorvinphos in the fat of cattle, goats, hogs, horses, sheep, and poultry; in eggs; and in milk fat (including negligible residues in whole milk).

Therefore, anticipated residue estimates incorporating percent livestock treated data will be used to estimate risk. Two methods were used to estimate the percentages. For dermal application of tetrachlorvinphos to cattle and poultry, percent lifestock treated estimates were obtained by OPP's Biologic and Economic Analysis Division using various public and private sources. These percentages are directly specified in Table 6. For all other livestock, the percents were estimated using application rates from labels.

ARs were used to estimate both chronic and upper bound carcinogenic dietary risk. The estimates provided (See Table 7) are based on data from metabolism studies which are the best available residue data. Some of the AR estimates exceed the current tolerance levels. This results from (1) use of nature of the residue data (metabolism studies) instead of magnitude of the residue data (due to the identified inadequacies), and (2) use of a revised tolerance expression which includes tetrachlovinphos and the four metabolites of concern.

Section 408(b)(2)(E) requires that if a tolerance relies on anticipated or actual residue levels, that the Agency make a determination every five years as to the reliability of the data, i.e. that the current residue levels are not above the levels relied on. To provide for the periodic evaluation of these anticipated residues, the Agency will require under Section 408(b)(2)(E) residue data to be submitted every 5 years as long as the tolerances remain in force.

Section 408(b)(2)(F) requires that if a tolerance relies on percent treated data, that the Agency make a determination as to the reliability of the data. The percent livestock-treated estimates were derived from a variety of sources. Typically, a range is assumed for the exposure assessment. By using this upper end estimate of percent livestock-treated, the Agency is reasonably certain that exposure is not understated for any significant population sub-group. Additionally, the DRES (Dietary Risk Evaluation System) modeling used in estimating chronic dietary risk uses regional consumption information to estimate exposure for four population sub-groups that are geographically based regions of the United States. To provide for the periodic evaluation of these estimates of percent treated, the Agency will require under Section 408(b)(2)(F) for periodic re-evaluation of the percent treated data as long as the tolerances remain in force.

It should be noted that these estimates are derived on the basis of certain assumptions and therefore may have a significant degree of uncertainty. It should be further emphasized that these estimates were made for the purpose of risk assessment only, since magnitude of the residue data were not available. Once the required studies have been submitted and evaluated, ARs for tetrachlorvinphos and its metabolites will be recalculated and the risk will be re-examined in light of this new information.

Table 6 - Estimates of Tetrachlorvinphos Usage Data on Livestock

Site	Pounds a.i. Per Animal[a]	Active Ingredient Used per Year[b] (Million lbs)	Number of Animals Treated [c] (Million)	Total Number of Animals[d] (Million)	Percentage of Animals Treated[e]
Cattle- Feed Through	0.1725	2.1	12.17	96	12.7
Cattle - Dermal	--	--	--	--	5 - 20[f]
Hogs	0.0661	0.24	3.6	111.3	3.18
Horses	0.1808	0.12	0.66	2.1	31
Poultry - Dermal	--	--	--	--	11
Houses	na	0.15	na	2.1	na
Other[g]	na	0.44	na	na	na
Total[h]		3.5	0		

na not available/applicable

a Pounds tetrachlorvinphos (a.i.) per animal was calculated using application rates to determine the amount of tetrachlorvinphos applied to the animal.

b The total use of tetrachlorvinphos per type of livestock was obtained from an EPA proprietary database that contains information about tetrachlorvinphos distribution in the U.S.
c Number animals treated = lbs active ingredient used/lbs used per animal.
d U.S. Dept. of Commerce, 1992 Census of Agriculture, Volume 1, part 51, October 1994
e Percent livestock treated = number animals treated/total number animals.
f In Texas the number of cattle dermally treated was estimated to be 18 to 20 percent. Texas is the major cattle producing State. In Oklahoma the number of cattle dermally treated was estimated to be 10 to 15 percent. In Wisconsin the number of cattle treated might be less than 5 percent. On the basis of these expert opinions, the number of cattle treated is reported to range from 5 to 20 percent.
g Information about the use of tetrachlorvinphos in livestock premises is not readily available. Similarly, information about treated dogs and cats is not available.
h Texas and Oklahoma are assumed to be the major states of tetrachlorvinphos livestock use.

Table 7 - Anticipated Residues of Tetrachlorvinphos and Metabolites in Animal Commodities

Commodity	Tetrachlorvinphos Plus Regulated Metabolites From Oral Nature of the Residue Studies[a] (ppm)	Tetrachlorvinphos Plus Regulated Metabolites From Dermal Nature of the Residue Studies[a] (ppm)	Refined Residues Using Percent Livestock Treated Data
Cattle, meat [loin muscle, round muscle]	*[<0.01, <0.01]*[b]	*[1.87, 0.01]*	0.077
Cattle, fat	0.06	0.10	0.028
Cattle, mbyp	0.50	0.13	0.090
Eggs	n/a	0.28	0.0308
Goats, meat	<0.01	1.87	0.387

Goats, fat	0.06	0.10	0.160
Goats, mbyp	0.50	0.13	0.630
Hogs, meat	<0.01	1.87	0.012
Hogs, fat	0.06	0.10	0.005
Hogs, mbyp	0.50	0.13	0.020
Horses, meat	<0.01	1.87	0.000
Horses, fat	0.06	0.10	0.000
Horses, mbyp	0.50	0.13	0.000
Milk	0.005	0.02	0.005
Poultry, meat *[breast muscle, thigh muscle]*	na[c]	*[0.059, 2.90]*	0.192
Poultry, fat	na[c]	6.94	0.763
Poultry, mbyp	na[c]	1.27	0.140
Sheep, meat	<0.01	1.87	0.000
Sheep, fat	0.06	0.10	0.000

Sheep, mbyp	0.50	0.13	0.000

a These concentrations represent parent plus four metabolites and are to be used for chronic and carcinogenic dietary risk evaluation.
b Apparent analytical limit of quantification (LOQ) 0.01 ppm; 1/2 LOQ 0.005 ppm.
c Not applicable. Not fed to poultry - only dermal uses for poultry.

b. Dietary (Drinking Water) Exposure

The Environmental Fate and Effects Division provided an assessment of the potential for tetrachlorvinphos to contaminate drinking water resources from the described uses. The following information sources were reviewed to determine the likelihood of tetrachlorovinphos to contaminate drinking water resources and thus, the need to estimate its concentrations in surface and ground water source drinking water: (1) draft RED dated September 10, 1995; (2) environmental fate data summary and memo from Bill Effland to Dennis McNeilly signed 8/16/94; (3) product label accepted 1/5/96 from Fermenta; and (4) readily available monitoring data.

The described label uses for tetrachlorvinphos indicate that it will be used outdoors for the purpose of treating areas near kennels, barns, recreational and picnic areas and other outdoor living areas for a variety of insects. However, for the most part, the area of coverage is generally small in most instances; less than an acre. This is substantiated by the method of delivery, pressurized knapsacks, which are not amenable to covering large areas. Furthermore, there are no approved scenarios for estimating surface water concentrations from these diffuse uses, although, it is possible to design a reasonable approach if necessary.

The environmental fate data on tetrachlorvinphos indicated that it is not very persistent in the environment, $t_{1/2}$ equals approximately 4 days. Mobility of tetrachlorvinphos in coarse soils may pose a potential for leaching to groundwater if not mitigated by biodegradation; however, in finer textured soils and soils with high organic content, tetrachlorvinphos was not very mobile. In all, tetrachlorvinphos is not likely to persist in soils or surface water, nor will it survive, intact, most conventional drinking water treatment processes long enough to pose a significant risk to drinking water from surface water sources. There is a small likelihood that tetrachlorvinphos may contaminate ground water drinking water resources. However, a review of monitoring data from the *Pesticides in Ground Water Database* indicated that in two studies, covering 173 wells, tetrachlorvinphos was not found.

Uses other than outdoors may result in releases of tetrachlorvinphos to aquatic environments either by direct discharge or through a municipal waste treatment facility followed by discharge to surface waters. In either case, these discharges would be regulated under state or national water discharge programs which would prohibit concentrations in the effluent that would

result in toxicity to aquatic organisms or the general population in most instances.

Considering the information above and the fact that there are no registered uses of tetrachlorvinphos on food/feed crops, there appears to be no need to conduct a drinking water assessment at this time.

c. Dietary (food source) Risk Assessment

Currently, tolerances for tetrachlorvinphos *per se* exist for alfalfa; apples; cherries; corn, grain (sweet and pop); cranberries; peaches; pears; tomatoes; and horse meat, fat and byproducts. However, there are no federally registered uses on these crops. HED has recommended that these tolerances be revoked. A label amendment is required to prohibit the treatment of horses destined for slaughter. Based on the assumption that until tolerances are revoked, that residues of tetrachlorvinphos could occur on an imported commodity, dietary risk was calculated both with and without these uses.

DRES analyses were performed to estimate chronic dietary risk for tetrachlorvinphos. HED uses the Dietary Risk Evaluation System (DRES) to combine the pesticide residue data with food consumption data. Thus, dietary (food source) exposure is equal to pesticide residues present in food multiplied by consumption data for the food item.

The consumption information used in this analysis is derived from USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). Over 30,000 respondents were surveyed over three days as to what foods they ate, with each individual's consumption information being associated with their body weight, sex, age, ethnicity and other sociodemographic information. Individual consumption estimates were weighted to be nationally representative. From these data single day and 3 day average consumption estimates were derived for the U.S. population and select population subgroups. Three day average information is used in the DRES chronic exposure analyses.

HED acknowledges that the data from this survey are approximately 20 years old. However, at this time, the data are the best information available to the Agency. USDA did conduct another NFCS in 1987-1988. However, the representativeness of these consumption data were called into question per a GAO Report due to the low response rate of certain groups. Therefore, the data are not used for routine risk assessment purposes. Another survey was conducted in 1989-1991, and also in 1994-1996. The 1994-1996 data are currently undergoing translation, which involves taking the consumed foods such as apple pie; breaking this into raw agricultural commodities such as sugar, apples, and flour; and then using standard recipes to reaggregate the amounts of sugar, apples and flour with all of the other foods consumed.

Note that a tiered approach is used for dietary risk assessment. The pesticide residue component is progressively refined proceeding from worst-case assumptions (such as tolerance level residues) to more realistic assumptions (such as use of monitoring data). Refinement of pesticide residues continues until no risk concern is indicated or a determination is made that

mitigation is required. This tiering approach conserves Agency resources.

Chronic (non-cancer) Dietary Risk

Tolerance level residues were used to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Refinements to residues were considered in calculating the Anticipated Residue Contribution (ARC) for those same population groups. Therefore, the ARC is considered to be the more realistic estimate of dietary exposure. These exposure estimates were then compared to the RfD for tetrachlorvinphos. Note that % RfDs have been rounded to two significant figures, 1 significant figure if less than 10%.

Table 8: Chronic (non-cancer) Dietary Risk
Analysis I

Using Tolerances: The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from **all published uses** are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.031951	80
Non-nursing Infants (< 1 year)	0.153108	380
Nursing Infants (< 1 year)	0.088606	220
Child (1- 6 years)	0.082572	210

Using Anticipated Residues: The Anticipated Residue Contribution (ARC) for the overall U.S. population from **all published uses** are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.023441	59
Non-nursing Infants (< 1 year)	0.117466	290
Nursing Infants (< 1 year)	0.079950	200
Child (1-6 years)	0.061191	150

Analysis II

Using Tolerances: The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from ***only*** **uses recommended through reregistration** are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.009036	23

Non-nursing Infants	0.036636	92
Nursing Infants (< 1 year)	0.009107	22
Child (1-6 years)	0.022481	56

Using Anticipated Residues: The Anticipated Residue Contribution (ARC) for the overall U.S. population from ***only*** **uses recommended through reregistration** are listed below.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.000525	1
Non-nursing Infants (< 1 year)	0.000994	2
Nursing Infants (< 1 year)	0.000451	1
Child (1 - 6 years)	0.001100	3

The chronic dietary risk from exposure to tetrachlorvinphos is much less than 100% of the RfD when (1) recommended uses only are considered, (2) percent livestock treated are incorporated, and (3) anticipated residues are used in the risk assessment.

Carcinogenic Dietary Risk

The upper bound carcinogenic risk from food uses of tetrachlorvinphos were calculated using the following equation:

$$\text{Upper Bound Cancer Risk} = \text{Dietary Exposure (ARC)} \times Q_1^*$$

Using the ARC, for the US population (see Analysis I - all published uses) and the tetrachlorvinphos Q_1^* of 1.83×10^{-3} $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be 4.3×10^{-5}, contributed through all the published uses for tetrachlorvinphos. However, only meat, milk, poultry, and egg tolerances are recommended for reregistration. When only meat, milk, poultry and eggs are considered the dietary cancer risk is 9.6×10^{-7}, for the U.S. population, 7.7×10^{-7} for adult males, and 7.2×10^{-7} for adult females (see Analysis II for ARC values).

All of these dietary risks are less than 1×10^{-6}.

Dietary Risk Characterization

As previously stated, ARs used in the upper bound carcinogenicity analysis may over-estimate risk due to lack of magnitude of the residue data for livestock. HED considers that the data used to perform these assessments were adequate. Overall, HED does not consider any of these estimates to under-represent residue levels and the corresponding risk estimates.

3. Occupational Exposure/Risk Assessment

An occupational and/or residential exposure assessment is required for an active ingredient

if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. For tetrachlorvinphos the toxicological criteria are triggered by the determination that tetrachlorvinphos is classified Group C, possible human carcinogen. Potential exposure does exist.

A. Uses Within the Scope of the Worker Protection Standard

The 1992 Worker Protection Standard (WPS) for Agricultural Pesticides established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food and feed crops). Uses within the scope of the WPS include uses on plants and uses on the soil or planting medium the plants are (or will be) grown in. To HED's knowledge, at this time none of the registered uses of tetrachlorvinphos are within the scope of the Worker Protection Standard for Agricultural Pesticides.

b. Occupational Handler (Mixer/Loader/Applicators) Exposure Assessment

In an occupational setting, tetrachlorvinphos is applied by hand application (e.g., treating cattle with dust formulation), hand and power sprayers and dusters, free-choice mineral blocks, granular feed supplements, dust boxes (for poultry), and pressurized aerosol cans. Application rates are "permit free access" (e.g., free-choice mineral blocks), and include specific maximum rates for cattle/swine and other farm animal treatments.

The Agency has determined that there is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with tetrachlorvinphos. Specifically, HED has concerns about potential exposures to tetrachlorvinphos arising from mixing and loading liquids, wettable powders, granulars, and from applying by aerosol can, dusters, pellets, power sprayers, low pressure handwands, and impregnated material.

Two mixer/loader/applicator (M/L/A) exposure studies were required per the Guidance for the Reregistration of Pesticide Products Containing Tetrachlorvinphos (October 1988). One indoor site and one outdoor site were required.

Chemical-specific M/L/A data for Rabon® 50 WP were generated using power sprayers for the interior of poultry houses (MRID 42622301). Note that this study is not in PHED, but has been used for illustrative purposes in this risk assessment. The acceptability of these data is pending the Agency's verification of the storage duration of the field samples versus the storage duration of the field recovery samples. This verification is necessary to validate the storage stability of tetrachlorvinphos.

Based on the use-patterns and potential exposures described above, the major exposure

scenarios were identified for tetrachlorvinphos. These exposure scenarios are: (1) mixing/loading liquids, (2) mixing/loading granular materials, (3a) mixing/loading wettable powder (data from MRID 42622301), (3b) mixing/loading wettable powder (data from PHED), (4) applying tetrachlorvinphos using a product in an aerosol can, (5) dusters, (6) pellets, (7) applying tetrachlorvinphos using power sprayers (data from MRID 42622301), (8) mixing, loading and applying tetrachlrvinphos using a low pressure handwand, and (9) mixing/loading/applying tetrachlorvinphos using a backpack sprayer.

Dermal and inhalation exposures are presented in Table 9. Chemical-specific data were submitted for scenarios 3b and 7. All other scenarios were estimated using PHED Version 1.1 surrogate data. The Pesticide Handlers Exposure Database (PHED) was developed by Health Canada, the American Crop Protection Association, and EPA. PHED was initially released for public use in 1992. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in the handling or application of pesticides in the field. The database currently contains data for over 2000 monitored exposure events. Use of surrogate or generic data is appropriate since it is generally believed that the physical parameters of the handling and application process (e.g. the type of formulations, the method of application, and the type of clothing), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than available from a single exposure study.

PHED also contains algorithms that allow the user to complete surrogate task-based exposure assessments beginning with one of the four main data files contained in the system (i.e., mixer/loader, applicator, flagger, and mixer/loader/applicator). Users select data from each file and construct exposure scenarios that are representative of the use of the chemical. HED, in conjunction with the PHED task force, has evaluated all of the data currently in PHED, and developed a surrogate exposure table that contains a series of standard exposure estimates for various scenarios. These standard unit exposure values are the basis for this assessment. The standard exposure values (i.e., the unit exposure values included in the exposure and risk assessment tables) are based on the “best fit” values calculated by PHED. PHED calculates “best fit” exposure values by assessing the distributions of exposures for each body part included in datasets selected for the assessment (e.g., chest or forearm) and then calculating a composite exposure value representing the entire body. PHED categorizes distributions as normal, lognormal, or in an “other” category. Generally, most data contained in PHED are lognormally distributed or fall into the PHED “other” distribution category. If the distribution is lognormal, the geometric mean for the distribution is used in the calculation of the “best fit” exposure value. If the data are an “other” distribution, the median value of the dataset is used in the calculation of the “best fit” exposure value. As a result, the surrogate unit exposure values that serve as the basis for this assessment generally range from the geometric mean to the median of the selected dataset.

HED’s first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a

long-sleeved shirt, and no chemical-resistant gloves. If, there is a level of concern, then increasing levels of appropriate risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to achieve an appropriate margin of exposure or cancer risk. Table 9 exposure estimates are baseline estimates.

Table 10 summarizes the clothing, equipment, and other assumptions used for each exposure scenario.

Table 9: Baseline Exposure Estimates for Occupational Uses of Tetrachlorvinphos (Mixer/Loader/Applicator)

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (mg/lb ai)	Maximum Label Application Rate[c]	Daily Max[d] Treated	Daily Dermal Dose[e] (mg/kg/day)	Daily Inhalation Dose[f] (mg/kg/day)	Total Daily Dose[g] (mg/kg/day)
Mixer/Loader Exposure							
Liquids (I)	2.9	0.0012	0.027 lb ai/cow	400 cattle	0.0428	0.000185	0.043
Granules (II)	0.0084	0.0017	0.14 lb ai/cow	400 cattle	0.000643	0.00136	0.002
Wettable Powder (IIIa) (data from MRID 42622301)	0.3 (gloves)	0.024	40 lb ai/poultry house	1 poultry house	0.016	.014	0.030
Wettable Powder (IIIb) (data from PHED)	3.7 (no gloves)	0.0434	40 lb ai/poultry house	1 poultry house	0.2023	0.0248	0.23
Applicator Exposure							
Aerosol Can (IV)	172	2.43	0.00433 lb ai/can	1 can	0.00102	0.000150	0.0012
Dusters (V)	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Power Sprayers (VII)	0.6 (gloves)	0.006	40 lb ai/poultry house	1 poultry house	0.033	.0034	0.036
Mixer/Loader/Applicator							
Low Pressure Handwand (VIII) (liquid open/pour)	102	0.30	1.4 lb ai/A	2.5 acre[i]	0.48807	0.015	0.50
Backpack (IX) [h]	483	0.329	1.4 lb ai/A	2.5 acre[i]	2.31125	0.01645	2.33

a Baseline dermal unit exposures represents workers wearing long pants, long-sleeved shirts, and no gloves. NOTE: For scenarios IIIb and VII workers wore chemical-resistant gloves in MRID 42622301.

b Baseline unit Inhalation exposure represents no respirator.

c Tetrachlorvinphos labels 4691-132, 4691-133, 4691-128 (previously 56493-29, 56493-34, 56493-13, which were transferred).

d Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

e The Daily Dermal Dose has been adjusted for dermal absorption based on the previously described dermal absorption study. HED assumed ten hours exposure (a typical work day) before washing any material from the skin. The value used (9.57%) is a combination of tetrachlorvinphos bound to the skin, that could not be washed off and is therefore available for absorption, and absorbed tetrachlorvinphos. (MRID 42111501)

Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)* Max. Appl. Rate (lb ai/cycle)* Max. Treated*.0957}}{\text{70 kg}}$

f Inhalation Daily Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)* Max. Appl. Rate (lb ai/cycle)* Max. Treated}}{\text{70 kg}}$

(Assumed 100 % absorption via the inhalation pathway.)

g Total Daily Dose = Daily Dermal Dose + Inhalation Daily Dose Note that the toltal daily dose has been rounded to two significant figures.

h Backpack is applicator only not mixer/loader/applicator due to low confidence data and lack of hand data for liquid (open/pour) backpack. See Table 10 for data quality for backpack applicator)

i The available information indicates that approximately 2.5 acres is appropriate.

Table 10: Exposure Scenario Descriptions for Tetrachlorvinphos

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Standard Assumptions[b]	Comments[c]
Mixer/Loader Exposure					
Liquids(I)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	Open Mixing/Loading	Treat cattle every 10 days for 6 months (i.e., 18 treatments) OR Treat cattle every 10 days for 12 months (i.e., 36 treatments)	**Baseline:** Hands, dermal , and inhalation acceptable grades; Dermal = 71 - 121 replicates; Hands = 53 replicates;Inhalation = 53 replicates; High confidence in dermal, hand, and inhalation data **PPE:** Hands, dermal , and inhalation acceptable grades; Dermal = 71 - 121 replicates; Hands = 59 replicates;Inhalation = 53 replicates; High confidence in dermal, hand, and inhalation data
Granules (II)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	Open Mixing/Loading	Feed to cattle every 10 days for 6 months (i.e., 18 treatments) OR Feed to cattle every 10 days for 12 months (i.e., 36 treatments)	**Baseline:** Hands = All grades; Hands = 10 replicates; Dermal = ABC grades; Dermal = 33 to 78 replicates; Low confidence in dermal and hands due to poor grade quality of the hand replicates and low replicate numbers. Inhalation = acceptable grades; Inhalations = 58 replicates; High confidence in inhalation data **PPE:** Dermal = ABC; dermal = 33 - 78 replicates; Hands = acceptable grades; Hands = 45 replicates; medium confidence in hands and dermal; inhalation = 58 replicates; inhalation = acceptable grades; High confidence in inhalation data
Wettable Powders (IIIa)	MRID 426223-01	Single Layer Coveralls, Gloves[a]	Open Mixing/Loading	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments) OR Treat once every 14 days for 12 months (26 treatments)	Acceptable grades (pending verification of storage stability); Dermal and inhalation = 16 replicates; High confidence in data (based on preliminary findings)

Wettable Powders (IIIb)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	Open Mixing/Loading	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments) OR Treat once every 14 days for 12 months (26 treatments)	**Baseline:** Dermal and Hands = ABC; dermal = 22 - 45 replicates; hands = 7 replicates; low confidnece in dermal and hands due to the low number of hand replicates; Inhalation = ABC; Inhalation = 44 replicates; Medium confidence in inhalation data **PPE:** Dermal, hands, and inhalation = ABC, dermal = 22 - 45 replicates; hands = 24 replicates; inhalation = 44 replicates; medium confidence in dermal, hands, and inhalation data
Applicator Exposure					
Aerosol Can (IV)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	Aerosol Can	1 can - 1 animal treated once per week for 6 months (26 treatments) OR 1 can - 1 animal treated once per week for 12 months (52 treatments)	**Baseline:** Dermal = 30 replicates; dermal = ABC; hand = 15 replicates; hand = A. Inhalation = 30 replicates; Inhalation = ABC; Medium confidence in inhalation, dermal and hand data. **PPE:** Dermal = 30 replicates; dermal = ABC; hand = 15 replicates; hand = A. Inhalation = 30 replicates; Inhalation = ABC; Medium confidence in inhalation, dermal and hand data.
Dusters (V)	No Data	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data	No Data
Power Sprayers (VII)	MRID 426223-01	Single Layer Coveralls, Gloves[a]	Wandtype Sprayers, Coarse Spray, Single Nozzle, 100 ft. long hose	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments) OR Treat once every 14 days for 12 months (26 treatments)	Acceptable grades (pending verification of storage stability); Dermal and inhalation = 16 replicates; High confidence in data (based on preliminary findings)
Mixer/Loader/Applicator					

Low Pressure Handwand (VIII)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	2 to 3 gallon low pressure single wand	1 acre treated once per week for 6 months (26 treatments) OR 1 acre treated once per week for 12 months (52 treatments)	**Baseline:** Inhalation = 80 replicates; Inhalation = ABC; dermal = 9 - 80 replicates; dermal = ABC; hands = 70 replicates; hands = all grades; Low confidence in hands and dermal data due to inadequate replicate number and low hand grades used (lots of E data). Medium confidence in inhalation data. **PPE:** Inhalation = 80 replicates; Inhalation = ABC; dermal = 13 replicates; dermal = C; hands = 10 replicates; hands = ABC; Low confidence in hands and dermal data due to inadequate replicate number. Medium confidence in inhalation data.
Backpack (IX)	PHED V1.1	Baseline: Long Pants, Long-Sleeved Shirt, No Gloves PPE: Long Pants, Long-Sleeved Shirt, Gloves	2 gallon backpack	1 acre treated once per week for 6 months (26 treatments) OR 1 acre treated once per week for 12 months (52 treatments)	**Minimal Clothing:** Dermal and Hands = Acceptable grades; dermal = 69 replicates; hands = 60 replicates; high confidence in hands and dermal data **Baseline:** Dermal and Hands = Acceptable grades; dermal = 69 replicates; hands = 60 replicates; high confidence in hands and dermal data. A 50% protection factor (PF) was applied on dermal, non-hand, -head, and -neck minimal clothing exposures to simulate baseline clothing (Long sleeve shirt, long pants, no gloves) Inhalation = acceptable grades; Inhalation = 40 replicates High confidence in inhalation data. **PPE:** Dermal and Hands = Acceptable grades; dermal = 69 replicates; hands = 60 replicates; high confidence in hands and dermal data. A 50% protection factor (PF) was applied on dermal, non-hand, -head, and -neck baseline clothing exposures to simulate PPE clothing (Long sleeve shirt, long pants, gloves) Inhalation = acceptable grades; Inhalation = 40 replicates High confidence in inhalation data.

a Clothing scenario represents actual monitored exposure data.

b Standard Assumptions based on an 8-hour work day as estimated by HED. The label specifes that treatment with larvicidal feeds should begin early in the spring before flies begin to appear and continue feeding throughout the summer and into fall until cold weather restricts fly activity. Depending on the area of the US, this could be as short as a few months or could encompass most of the year. Therefore, the assessment was performed for 6 month and 12 month scenarios.

c These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. A replicate refers to data acquired during one complete work cycle. All handler exposure assessments in this document are based on the "Best Available" data as defined by HED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments.) Best available grades are assigned as follows: matrices with grades A and B data (which is defined as acceptable grade data) and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data (all grades) regardless of the quality and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor.

Data confidence as reported in the Table refers to both the quality and the quantity (number of replicates) of data for each PHED run. Each study in PHED has been graded from A to E. A high confidence run is grades A and B data and 15 or more replicates per body part. Any combination of A and B grade data are listed as acceptable grades data in the tables. A medium confidence run is grades A, B, and C data and 15 or more replicates per body part. Any combination of A, B, and C grade data are listed as ABC grade data in the tables. A low confidence run is all grades (any run that includes D or E grade data) or has less than 15 replicates per body part.

c. Occupational Handler Risk Assessment

Table 11: Baseline Risk Estimates for Occupational Uses of Tetrachlorvinphos

Exposure Scenario (Scenario #)	Total Daily Dose[a] (mg/kg/day)	Mixer/Loader/Applicator	
		LADD[b] (mg/kg/day)	RISK[c] (mg/kg/day)
Mixer/Loader Exposure			
Liquids (I)	0.043	(Dose)(18/365)(35/70) = 0.0010597	1.9×10^{-6}
		(Dose)(36/365)(35/70) = 0.0021195	3.8×10^{-6}
Granules (II)	0.002	(Dose)(18/365)(35/70) = 0.0000493	9.0×10^{-8}
		(Dose)(36/365)(35/70) = 0.0000986	1.8×10^{-7}
Wettable Powder (IIIa) MRID 42622301 (gloves)	0.030	(Dose)(13/365)(35/70) = 0.000534	9.7×10^{-7}
		(Dose)(26/365)(35/70) = 0.001068	1.9×10^{-6}
Wettable Powder (IIIb) PHED (no gloves)	0.23	(Dose)(13/365)(35/70) = 0.0040442	7.4×10^{-6}
		(Dose)(26/365)(35/70) = 0.0080884	1.5×10^{-5}
Applicator Exposure			
Aerosol Can (IV)*	0.0012	(Dose)(26/365)(35/70) = 0.0000416	7.6×10^{-6}
		(Dose)(52/365)(35/70) = 0.0000833	1.5×10^{-7}
Dusters (V)*	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data
Power Sprayers (VII)	0.036	(Dose)(13/365)(35/70) = 0.0006482	1.2×10^{-6}
		(Dose)(26/365)(35/70) = 0.001296	2.3×10^{-6}
Mixer/Loader/Applicator			
Low Pressure Handwand (VIII)	0.50	(Dose)(26/365)(35/70) = 0.01792	3.3×10^{-5}
		(Dose)(52/365)(35/70) = 0.03582	6.6×10^{-5}
Backpack (IX)	2.33	(Dose)(26/365)(35/70) = 0.0829	1.5×10^{-4}
		(Dose)(52/365)(35/70) = 0 0.1658	3.0×10^{-4}

a Total Daily Dose was estimated in Table 9
b LADD (mg/kg/day) = [Daily Dermal Dose + Daily Inhalation Dose(mg/kg/day)] * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs)
c Risk = LADD (mg/kg/day) * (Q_1 *); where $Q_1^* = 1.83 \times 10^{-3}$ mg/kg/day^{-1}.

All carcinogenic risks are in the 10^{-6} or lower risk range with the exception of scenarios IIIb, VIII, IX, and X. Mitigation (use of PPE) can reduce the risk. (See Table 12)

Table 12: PPE (Personal Protective Equipment) Risk Estimates for Occupational Uses of Tetrachlorvinphos

Exposure Scenario (Scenario #)	Total Daily Dose (mg/kg/day)	LADD[a] (mg/kg/day)	RISK[b] (mg/kg/day)
Mixer/Loader			
Wettable Powder (IIIb) PHED[c]	0.034	(Dose)(13/365)(35/70) = 0.0006054	1.1×10^{-6}
		(Dose)(26/365)(35/70) = 0.0012109	2.2×10^{-6}
Mixer/Loader/Applicator			
Low Pressure Handwand (VIII)[d]	0.017	(Dose)(26/365)(35/70) = 0.0006054	1.1×10^{-6}
		(Dose)(52/365)(35/70) = 0.0012109	2.2×10^{-6}
Backpack (IX)[e]	1.14	(Dose)(26/365)(35/70) = 0.0406027	7.4×10^{-5}
		(Dose)(52/365)(35/70) = 0.0812054	1.5×10^{-4}
Backpack (IX)[f]	0.67	(Dose)(26/365)(35/70) = 0.023863	4.4×10^{-5}
		(Dose)(52/365)(35/70) = 0.047726	8.7×10^{-5}

a LADD (mg/kg/day) = [Daily Dermal Dose + Daily Inhalation Dose(mg/kg/day)] * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs)
b Risk = LADD (mg/kg/day) * (Q_1 *); where $Q_1^* = 1.83 \times 10^{-3}$ mg/kg/day^{-1}.
c PPE dermal unit exposure = 0.167 mg/lb ai (single layer clothing, gloves - see Table 10 for assumptions)
Using the calculation in Table 9 footnotes, daily dermal dose = (0.167)(40)(1)(0.0957) / (70) = 0.0091325 mg/kg/day
Daily Inhalation Dose (See Table 9) = 0.0248 mg/kg/day
Total Daily Dose = 0.0091325 + 0.0248 = 0.034 mg/kg/day
d PPE dermal unit exposure = 0.427 mg/lb ai (single layer clothing, gloves - see Table 10 for assumptions)

Using the calculation in Table 9 footnotes, daily dermal dose = (0.427)(1.4)(2.5)(0.0957) / (70) = 0.0020431 mg/kg/day
Daily Inhalation Dose (See Table 9) = 0.015 mg/kg/day
Total Daily Dose = 0.0020431 +0.015 = 0.017 mg/kg/day

e PPE dermal unit exposure = 234 mg/lb ai (single layer clothing, gloves - see Table 10 for assumptions)
Using the calculation in Table 9 footnotes, daily dermal dose = (234)(1.4)(2.5)(0.0957) / (70) = 1.11969 mg/kg/day
Daily Inhalation Dose (See Table 9) = 0.01645 mg/kg/day
Total Daily Dose = 1.11969 + 0.01645 = 1.14 mg/kg/day

f PPE dermal unit exposure = 135.8 mg/lb ai (double layer clothing, gloves - see Table 10 for assumptions)
Using the calculation in Table 9 footnotes, daily dermal dose = (135.8)(1.4)(2.5)(0.0957) / (70) = 0.649803 mg/kg/day
Daily Inhalation Dose (See Table 9) = 0.01645
Total Daily Dose = 0.649803+ 0.01645 = 0.67 mg/kg/day

For scenario IIIb (wettable powder - PHED), the use of gloves gives a risk that is comparable to that estimated using data obtained in MRID 42622301, in which the test subjects also wore gloves. Mitigation for scenarios VIII, IX, and X can reduce the risk by an order of magnitude.

d. Occupational Post-Application Exposure

None of the registered uses of tetrachlorvinphos are within the scope of the Worker Protection Standard for Agricultural Pesticides. Therefore, REIs (restricted-entry intervals) are not required on the labels of products containing tetrachlorvinphos. Tetrachlorvinphos can be used as a feed-through. Given the mechanized systems for feed delivery in most feed-lots and the nature of manure removal, HED believes that post-application exposure should be minimal and certainly less than that of mixing/loading. (Note that the risk estimates for mixing/liquid or granular tetrachlorvinphos in the feed are 10^{-6} or less.

However, HED has determined that there is potential exposure to persons entering treated sites, such as poultry houses in which tetrachlorvinphos is applied on surface areas, after application is complete. HED specifically was concerned about potential post-application exposure arising from re-entering these indoor premises. Given the nature of activities performed in a poultry house, such as visually checking the condition of the caged birds, as well as feeding, and watering, contact with treated surfaces should be minimal. Therefore, the potential for dermal post-application exposure should be minimal. There was also concern for inhalation post-application exposure since poultry houses are confined spaces. However, the vapor pressure of tetrachlovinphos is 2.6×10^{-7} mm Hg at 25 C, and the acute inhalation toxicity is category III. Therefore, post-application inhalation exposure should be minimal.

Thus, based on the use patterns for this chemical the potential for post-application exposure should be minimal. Therefore, post-application exposure data are not required.

4. Residential Exposure/Risk Assessment

There are various tetrachlorvinphos products for control of ticks and fleas on dogs and cats. A REFs search conducted on 11/7/97 identified 107 products containing tetrachlorvinphos. End-use products with residential uses are marketed in the following formulations: impregnated collars, powders/dusts, emulsifiable concentrates, spray cans (pressurized liquids), ready-to-use pump sprays and wettable powders. No tetrachlorvinphos-specific data are available, therefore estimates were made using the best available data and the professional judgements of the HED staff. The draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments were used for estimating dermal exposure, as well as the available data (aerosol spray) in PHED.

Only a carcinogenic assessment, using a Q_1^* of 0.00183 $(mg/kg/day)^{-1}$, was performed since there are no short-term or intermediate-term endpoints of concern. A chronic assessment was not performed since there is no chronic residential exposure scenario. Carcinogenic assessments are performed for adults only, assuming a 70 kg adult body weight.

Table 13 presents the residential applicator scenarios, both exposure and risk.
Tables 14A and 14B present the post-application scenarios, both exposure and risk.
Table 15 presents the residential aggregate scenarios, both exposure and risk.

Note that the label information and some of the assumptions used are in the Tables. More assumptions as well as the calculations used are in the Table footnotes.

Table 13: Residential Applicator Scenarios - Carcinogenic Assessment of Residential Uses of Tetrachlorvinphos

Use	Label Information	Assumptions	Absorbed Daily Dermal Dose (mg/kg/day)	LADD[1] (mg/kg/day) Amortization	Risk[2]
Dip[3]	Label 2596-119 bottle contains 8 ounces (236 mls) of product that is 2.8% tetrachlorvinphos, 2 oz of product is mixed with a gallon water Label states "repeat as necessary for control"	Amount of product handled: either 2 oz yielding 1 gallon or 8 oz yielding 4 gallons - depends on size of pet, and whether pet-owner is sponging on pet, or actually immersing the pet dermal absorption factor is 9.57% 10% of the active ingredient applied to the pet is assumed to be the amount the pet-owner is exposed to during dipping 0.8 g/ml = estimated density factor of product adult body weight is 70 kg	make 1 gallon 0.18068	(Dose)(5/365)(20/70) = 0.00070716	1.3×10^{-6}
				(Dose)(5/365)(40/70) = 0.0014143	2.5×10^{-6}
				(Dose)(12/365)(20/70) = 0.0016971	3.1×10^{-6}
				(Dose)(12/365)(40/70) = 0.0033943	6.2×10^{-6}
			make 4 gallons 0.72273	(Dose)(5/365)(20/70) = 0.0028286	5.1×10^{-6}
				(Dose)(5/365)(40/70) = 0.0056573	1.0×10^{-5}
				(Dose)(12/365)(20/70) = 0.0067888	1.2×10^{-5}
				(Dose)(12/365)(40/70) = 0.0135778	2.5×10^{-5}

Spray Can[4]	Label 2596-122 can is 7 ounces (198 g) which is 1.08 % tetrachlorvinphos by weight Label states "repeat spray once every few days until infestation is brought under control, then repeat as necessary"	Homeowner could spray the entire can or half the can. The amount sprayed would depend on the size of the pet, and if bedding or other house nsurfaces are sprayed. dermal absorption factor is 9.57% inhalation absorption is assumed to be 100% or 1 adult body weight is 70 kg PHED data available for an aerosol can: 219 mg/lb ai - dermal 2.4 mg/lb ai - inhalation (inhalation = 30 replicates, dermal = 30 replicates, hands = 15 replicates, all medium confidence due to use of A,B,C data, assumes minimal clothing - short sleeves, short pants, and no gloves)	Entire Can dermal = 0.0014102 inhalation = 0.0001614 Total = 0.0015716	(Dose)(5/365)(20/70) = 0.000006	1.1×10^{-8}
				(Dose)(5/365)(40/70) = 0.0000123	2.3×10^{-8}
				(Dose)(12/365)(20/70) = 0.0000147	2.7×10^{-8}
				(Dose)(12/365)(40/70) = 0.0000295	5.4×10^{-8}
			Half the Can dermal = 0.0007051 inhalation = 0.0000807 Total = 0.0007858	(Dose)(5/365)(20/70) = 0.000003	5.7×10^{-9}
				(Dose)(5/365)(40/70) = 0.0000061	1.1×10^{-8}
				(Dose)(12/365)(20/70) = 0.0000073	1.4×10^{-8}
				(Dose)(12/365)(40/70) = 0.0000147	2.7×10^{-8}
Powder[5]	Labels 2596-78, 2596-79, 4691-138 container is 4 ounces (113 g) which is 3 % tetrachlorvinphos Label 2596-78 states "lasts 7 days...repeat at weekly internals if necessary" Label 4691-138 states "kills fleas up to 16 days...kills ticks up to 7 days...repeat at weekly intervals if necessary"	Amount of product handled depends on size of pet, and if bedding is also being treated dermal absorption factor is 9.57% 10% of the active ingredient applied to the pet is assumed to be the amount the pet-owner is exposed to during treatment adult body weight is 70 kg	Half the Container 0.2317	(Dose)(5/365)(20/70) = 0.0009068	1.7×10^{-6}
				(Dose)(5/365)(40/70) = 0.0018136	3.3×10^{-6}
				(Dose)(12/365)(20/70) = 0.0021764	4.0×10^{-6}
				(Dose)(12/365)(40/70) = 0.0043528	8.0×10^{-6}
			Entire Container 0.4635	(Dose)(5/365)(20/70) = 0.001814	3.3×10^{-6}
				(Dose)(5/365)(40/70) = 0.0036281	6.6×10^{-6}
				(Dose)(12/365)(20/70) = 0.0043538	8.0×10^{-6}
				(Dose)(12/365)(40/70) = 0.0087076	1.6×10^{-5}

Pet collars[6]	Labels 2596-62, 2596-139, 2596-63 All collars contain 14.55% tetrachlovinphos. The weight of the collar varies due to the size of the anumal, varying for puppies to large dogs 19 to 33 g, for cats 12 to 15 g. The largest cat or dog collar was used for this assessment.	dermal absorption factor is 9.57%. adult body weight is 70 kg Assume that 2 collars are used/year. One percent of the active ingredient in the flea collars is assumed to be the amount the pet-owner is exposed to during handling of the collars.	Cat 0.0000298	(Dose)(2/365)(20/70) = 4.665×10^{-8}	8.5×10^{-11}
				(Dose)(2/365)(40/70) = 9.33×10^{-8}	1.7×10^{-10}
			Dog 0.0000656	(Dose)(2/365)(20/70) = 1.02×10^{-7}	1.9×10^{-10}
				(Dose)(2/365)(40/70) = 2.05×10^{-7}	3.8×10^{-10}
Pump sprays[7]	Labels: 2596-126 (cats), 2596-125 (dogs) 28293-27 (horses) For cats the container is 8 fl oz (236 mL) which is 1.08% tetrachlorvinphos by weight. For dogs the container is 14.5 fl oz (428 mL) which is 1.08% tetrachlorvinphos by weight. For horses the container is 1 quart which is 1% tetrachlorvinphos by weight.	For dogs and cats, the pet-owner could spray one quarter or one half the container. The amount sprayed would depend on the size of the pet, and if bedding or other house surfaces are also being treated. It is considered unlikely that the entire bottle would be used on one animal. For horses the label specifies to use no more than 2 ounces per horse. dermal absorption factor is 9.57% 10% of the active ingredient applied to the pet is assumed to be the amount the pet-owner is exposed to during spraying. 0.8 g/mL = estimated density factor of product adult body weight is 70 kg	Cat One Half Bottle (4 fl.oz.) 0.13938	(Dose)(5/365)(20/70) = 0.0005455	1.0×10^{-6}
				(Dose)(5/365)(40/70) = 0.001091	1.9×10^{-6}
				(Dose)(12/365)(20/70) = 0.0013092	2.3×10^{-6}
				(Dose)(12/365)(40/70) = 0.0026184	4.7×10^{-6}
			Cat One Quarter Bottle (2 fl.oz.) 0.06969	(Dose)(5/365)(20/70) = 0.0002727	5.0×10^{-7}
				(Dose)(5/365)(40/70) = 0.0005455	1.0×10^{-6}
				(Dose)(12/365)(20/70) = 0.0006546	1.1×10^{-6}
				(Dose)(12/365)(40/70) = 0.001309	2.3×10^{-6}
			Dog One Half Bottle (7.25 fl.oz.) 0.252779	(Dose)(5/365)(20/70) = 0.0009893	1.8×10^{-6}
				(Dose)(5/365)(40/70) = 0.0019787	3.6×10^{-6}
				(Dose)(12/365)(20/70) = 0.0023744	4.3×10^{-6}
				(Dose)(12/365)(40/70) = 0.0047488	8.6×10^{-6}

			Dog One Quarter Bottle (3.62 fl.oz.) 0.12639	(Dose)(5/365)(20/70) = 0.0004946	9.1×10^{-7}
				(Dose)(5/365)(40/70) = 0.0009893	1.8×10^{-6}
				(Dose)(12/365)(20/70) = 0.001187	2.2×10^{-6}
				(Dose)(12/365)(40/70) = 0.002374	4.3×10^{-5}
			Horse 2 fl. oz. 0.06466	(Dose) (26/365)(20/70) = 0.001316	2.4×10^{-6}
				(Dose) (26/365)(40/70) = 0.002632	4.8×10^{-6}
				(Dose) (52/365)(20/70) = 0.002632	4.8×10^{-6}
				(Dose) (52/365)(40/70) = 0.005264	9.6×10^{-6}

1 LADD (lifetime average daily dose) = (absorbed dermal dose)(amortization factor described in table, which is number of treatment days per year/365, and number of years of pet ownership/70 year lifetime)

There is some data available on use of pesticides in and around the home. The National Home and Garden Pesticide Use Survey (NHGPUS) is a one-time survey of the use of pesticides in and around homes in the 48 co-terminous States and the District of Columbia. Data were collected for the 12 month period ending on the date of the interview. Interviews were conducted in August and September 1990 at 2,078 residences (households). The data from NHGPUS interviews indicated that: (1) the 95% confidence interval for use of a flea or tick collar is 13.79% to 19.07%, (2) 1.92% of the households surveyed applied pesticide products to cats and dogs 1 time in the past year, (3) 1.76% of the households surveyed applied pesticide products to cats and dogs 2 times in the past year (4) 3.31% of the households surveyed applied pesticide products to cats and dogs 3 to 6 times in the past year, (5) 2.66% of the households surveyed applied pesticide products to cats and dogs 7 to 12 times in the past year, (6) 3.20% of the households surveyed applied pesticide products to cats and dogs 13 to 52 times in the past year, and (7) < 1% of the households surveyed applied pesticide products to cats and dogs 53 to 104 times in the past year

Thus, HED does not have any data on how often a pet owner would use a specific type of product such as a dip, powder, or spray to treat a dog or cat, or on whether the product contained tetrachlorvinphos. The 5/365 is based on the assumption that some pet owners would treat their pet to get rid of a flea and tick infestation, and would then stop treatment. The 12/365 is based on the assumption that some owners would treat their pet on a routine basis as a preventive measure. These are considered to be reasonable assumptions.

HED does not have any data on how often a horse owner would spray or wipe a horse for control of flies, gnats, and mosquitos. Since no application interval was specified on the label, the assumptions for the occupational scenario of once a week for either 6 months or 12 months will be used.

For cat and dog collars, it is assumed that two collars per year are used.

There are also no data on how many pets, considering both cats and dogs, could be owned by the same owner at the same time, or for how many years an owner would have either one dog or cat, or a succession of different dogs and cats. Twenty and 40 years are considered to be reasonable assumptions.

2 Lifetime Cancer Risk = (LADD)(Q_1^*), where the Q_1^*, is 0.00183 $(mg/kg/day)^{-1}$

3 The dip scenario was estimated using a procedure similar to the one described in the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, specifically 9.1.1.

Dermal dose = (amount of liquid in bottle in mLs)(density factor) (percent ai)(conversion factor mg to g)(percent of ai pet-owner exposed to)/(portion of bottle used) (body weight in kg)
Absorbed dermal dose for 2 ounces or 1/4 bottle = (236 mLs) (0.8 g/mL) (0.028) (1000) (0.1) / (4)(70 kg) = 1.888 mg/kg/day (0.0957 dermal absorption factor) = 0.18068 mg/kg/day
Absorbed dermal dose for the entire 8 ounce bottle = (236 mLs) (0.8 g/mL) (0.028) (1000) (0.1)/ (70 kg) = 7.552 mg/kg/day (0.0957 dermal absorption factor) = 0.72273 mg/kg/day

4 Dermal dose = (PHED dermal unit exposure in mg/lb ai)(total grams in can)(percent ai in can)(conversion factor grams to lbs) / (portion of can used)(body weight in kgs)
Note that the PHED values represent a pet owner wearing short pants, and short sleeved shirt. No gloves are assumed. The 219 mg/lb ai dermal unit exposure is a combination of head and neck exposures; upper and lower arm, chest, back, thigh, and lower leg exposures; and hand exposures. There were 30 dermal replicates, ABC grade data. There are 15 hand replicates, A grade data. Medium confidence is attached to the dermal data due to the use of C grade data. The 2.4 mg/lb ai inhalation unit exposure is ABC grade data, 30 replicates. Medium confidence is also attached to the inhalation data due to the used of C grade data.

Absorbed dermal dose if the entire can is used = (219 mg/lb ai)(198 g/can)(0.0108) / (454 g/lb)(70 kg) = 0.0147359 mg/kg/day (0.0957 dermal absorption factor) = 0.0014102 mg/kg/day
Absorbed dermal dose if half the can is used = (219 mg/lb ai)(198 g/can)(0.0108) / (454 g/lb)(2)(70 kg) = 0.0073679 mg/kg/day (0.0957 dermal absorption factor) = 0.0007051mg/kg/day

Inhalation dose if the entire can is used = (2.4 mg/lb ai)(198 g/can)(0.0108) / (454 g/lb)(70 kg) = 0.0001614 mg/kg/day
Inhalation dose if half the can is used = (2.4 mg/lb ai)(198 g/can)(0.0108) / (454 g/lb)(2)(70 kg) = 0.0000807 mg/kg/day

5 The powder scenario was estimated using a procedure similar to the one described in the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, specifically 9.1.1.

Dermal dose = (amount of powder in container in g) (percent ai)(conversion factor mg to g)(percent of ai pet-owner exposed to) / (portion of container used) (body weight in kg)
Absorbed dermal dose for half the container = (113 g) (0.03) (1000) (0.1) / (2)(70 kg) = 2.4214 mg/kg/day (0.0957 dermal absorption factor) = 0.2317 mg/kg/day
Absorbed dermal dose for the entire container = (113 g) (0.03) (1000) (0.1)/ (70 kg) = 4.8429 mg/kg/day (0.0957 dermal absorption factor) = 0.4635 mg/kg/day

6 The collar scenario was estimated using a procedure similar to the one described in the draft Standard Operating Procedures (SOPs) for Residential

Exposure Assessments, specifically 9.1.1.

Dermal dose = (weight of collar in g)(percent ai)(0.01) / (70 kg)
Absorbed dermal dose for one CAT collar = (15 g)(0.1455)(0.01) / (70 kg) = 0.0003117 mg/kg/day (0.0957 dermal absorption factor) = 0.0000298 mg/kg/day
Absorbed dermal dose for one DOG collar = (33 g)(0.1455)(0.01) / (70 kg) = 0.0006859 mg/kg/day (0.0957 dermal absorption factor) = 0.0000656 mg/kg/day

7 The spray pump scenario was estimated using a procedure similar to the one described in the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, specifically 9.1.1.

Dermal dose = (amount of liquid in pump bottle in mLs)(density factor) (percent ai)(conversion factor mg to g)(percent of ai pet-owner exposed to) / (portion of bottle used) (body weight in kg)
For cats, the absorbed dermal dose for one-half the bottle = (236 mLs)(0.8)(0.0108)(1000)(0.1) / (2)(70) = 1.4564 mg/kg/day (0.0957 dermal absorption factor) = 0.13938 mg/kg/day
For cats, the absorbed dermal dose for one-quarter the bottle = (236 mLs)(0.8)(0.0108)(1000)(0.1) / (4)(70) = 0.72823 mg/kg/day (0.0957 dermal absorption factor) = 0.06969 mg/kg/day
For dogs, the absorbed dermal dose for one-half the bottle = (428 mLs)(0.8)(0.0108)(1000)(0.1) / (2)(70) = 2.64137 mg/kg/day (0.0957 dermal absorption factor) = 0.252779 mg/kg/day
For dogs, the absorbed dermal dose for one-quarter the bottle = (428 mLs)(0.8)(0.0108)(1000)(0.1) / (4)(70) = 1.32069 mg/kg/day (0.0957 dermal absorption factor) = 0.12639 mg/kg/day
For horses the absorbed dermal dose for 2 ounces = (946 mls)(0.8)(0.1)(1000)(0.1) / (16)(70) = 0.67571 mg/kg/day (0.0957 dermal absorption factor) = 0.06466 mg/kg/day

Post application scenarios assume that residues can be transferred from the pet to the skin of the pet-owner and thus available for dermal absorption, when contacting a treated dog or cat. The scenarios were estimated using a procedure similar to the one described in the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, specifically 9.2.1.

Table 14A: Adult Post-Application Exposures - Carcinogenic Assessment of Residential Uses of Tetrachlorvinphos

Days After Treatment (DAT)[1]	Absorbed Dermal Dose by Scenario (mg/kg/day)					
	Dip (1 gallon)	Dip (4 gallons)	Aerosol Spray (entire can)	Aerosol Spray (half can)	Powder (container)	Powder (Half container)
Day 0	0.0361363	0.1445452	0.0000282	0.0000141	0.0926922	0.0463461
Day 1	0.0051623	0.0206493	0.000004	0.000002	0.0132417	0.0066208
Day 2	0.0007374	0.0029499	0.0000005	0.0000002	0.0018916	0.0009458
Day 3	0.0001053	0.0004214	---	---	0.0002702	0.0001351
Day 4	0.000015	0.0000602	---	---	0.0000386	0.0000193
Day 5	0.0000021	0.0000086	---	---	0.0000055	0.0000027
Day 6	0.0000003	0.0000012	---	---	0.0000007	0.0000003
TWA[2]	0.0060226	0.0240908	0.0000109	0.0000054	0.0154486	0.0077243
Risk[3]						
Amortization Values for Estimating Risk						
(35/365)(20/70)	3.0×10^{-7}	1.2×10^{-6}	2.3×10^{-10} [4]	1.2×10^{-10} [4]	7.7×10^{-7}	3.9×10^{-7}
(35/365)(40/70)	6.0×10^{-7}	2.4×10^{-6}	4.7×10^{-10}	2.3×10^{-10}	1.5×10^{-6}	7.7×10^{-7}
(84/365)(20/70)	7.2×10^{-7}	2.9×10^{-6}	5.6×10^{-10}	2.8×10^{-10}	1.9×10^{-6}	9.3×10^{-7}
(84/365)(40/70)	1.4×10^{-6}	5.8×10^{-6}	1.1×10^{-9}	5.6×10^{-10}	3.7×10^{-6}	1.9×10^{-6}

Table 14B: Adult Post-Application Exposures - Carcinogenic Assessment of Residential Uses of Tetrachlorvinphos

Days After Treatment (DAT)[1]	Absorbed Dermal Dose by Scenario (mg/kg/day)					
	Collar cat	Collar dog	Pump Spray cat one-half container	Pump Spray cat one-quarter container	Pump Spray dog one-half container	Pump Spray dog one-quarter container
Day 0	not estimated	not estimated	0.0278765	0.0139382	0.0505558	0.0252779
Day 1			0.0039823	0.0019911	0.0072222	0.0036111
Day 2			0.0005689	0.0002844	0.0010317	0.0005158
Day 3			0.0000812	0.0000406	0.0001473	0.0000736
Day 4			0.0000116	0.0000058	0.000021	0.0000105
Day 5			0.0000016	0.0000008	0.000003	0.0000015
Day 6			0.0000002	0.0000001	0.0000004	0.0000002
TWA[2]			0.0046460	0.002323	0.0084259	0.0042129
Risk[3]						
Amortization Values for Estimating Risk (35/365)(20/70)	---	---	2.3×10^{-7}	1.2×10^{-7}	4.2×10^{-7}	2.1×10^{-7}
(35/365)(40/70)	---	---	4.7×10^{-7}	2.2×10^{-7}	8.4×10^{-7}	4.2×10^{-7}
(84/365)(20/70)	---	---	5.6×10^{-7}	2.8×10^{-7}	1.0×10^{-6}	5.1×10^{-7}
(84/365)(40/70)	---	---	1.1×10^{-6}	5.6×10^{-7}	2.0×10^{-6}	1.0×10^{-6}

Table 14C: Adult Post-Application Exposures - Carcinogenic Assessment of Residential Uses of Tetrachlorvinphos

Days After Treatment (DAT)[1]	Absorbed Dermal Dose by Scenario (mg/kg/day)
Day 0	0.012933
Day 1	0.0018475
Day 2	0.0002639
Day 3	0.0000377
Day 4	0.0000053
Day 5	0.0000007
Day 6	0.0000001
TWA[2]	0.0021554
Risk[3]	
Amortization Values for Estimating Risk	5.6×10^{-7}
(182/365)(20/70)	
(182/365)(40/70)	1.1×10^{-6}
(364/365)(20/70)	1.1×10^{-6}
(364/365)(40/70)	2.2×10^{-6}

1 The absorbed dose is estimated in a manner similar to that used in the Applicator Table. For post-application exposure it is assumed that 0.2 or 20% of the application rate is retained on the pet (dog, cat, or horse)as dislodgeable residue, and 0.1 or 10% of the residue is transferred to the pet-owner for all scenarios except collars. The dermal absorption factor is 0.0957.

The dermally absorbed dose (Day 0) = (active ingredient handled mg/day)(0.2)(0.1)(0.0957) / (70 kg)
The assumptions for active ingredient handled were taken from Table 13:

Dip (1 gallon) - (236 mLs)(0.8 g/mL)(0.028)(1000) / (4)
Dip (4 gallons) - (236 mLs)(0.8 g/mL)(0.028)(1000)
Aerosol spray (entire can) - (219 mg/lb ai)(198 g/can)(0.0108) / (454)
Aerosol spray (one-half can) - (219 mg/lb ai)(198 g/can)(0.0108) / (454)(2)
Powder (container) - (113 g)(0.03)(1000)
Powder (one-half container) - (113 g)(0.03)(1000) / (2)
Pump spray (cats - one-half) - (236 mLs)(0.8)(0.0108)(1000) / (2)
Pump spray (cats - one-quarter) - (236 mLs)(0.8)(0.0108)(1000) / (4)
Pump spray (dogs - one-half) - (428 mLs)(0.8)(0.0108)(1000) / (2)
Pump spray (dogs - one-quarter) - (428 mLs)(0.8)(0.0108)(1000) / (4)
Pump spray (horses) - (946 mLs)(0.8)(0.1) / (16)

For Day(1) to (6), the dermally absorbed dose is decreased each day by 1/7, based on label instructions to repeat every few days, as necessary, or weekly.

2 Time Weighted Average is the sum of the doses divided by the number of days.

3 Risk = (TWA)(Q_1^* which is 0.00183)(amortization). The amortization is 35/365 which considers 7 days of post-application exposure for each of the 5 treatments, or 84/365 which considers 7 days of post-application exposure for each of the 12 treatments. If the estimated post-application exposures demonstrate less than 7 days, then this estimate (see note 4) is used in the estimation. The 20/70 and 40/70 as used in the application scenario are also used for post-application scenarios.

4 For the Aerosol spray can, the absorbed daily dose was in the 10^{-7} range at Day 2. Therefore, the TWA for this scenario only is a three day average. Therefore, amortization should be 15/365, and 36/365 to account for the shorter (three day) post-application exposure.

Table 15: Aggregate Residential Risk - Adult Handler and Post-Application Risk

Scenario	Handler Risk	Post-Application Risk	Total Risk
dip (4 gallons) (12/365)(40/70)	2.5×10^{-5}	5.8×10^{-6}	3.1×10^{-5}
aerosol can (entire can) (12/365)(40/70)	5.4×10^{-8}	1.1×10^{-9}	5.5×10^{-8}
powder (entire container) (12/365)(40/70)	1.6×10^{-5}	3.7×10^{-6}	2.0×10^{-5}
pump spray (dog) (one-half bottle) (12/365)(40/70)	4.3×10^{-6}	2.0×10^{-6}	6.3×10^{-6}
dip (4 gallons) (5/365)(40/70) and powder (entire container) (5/365)(40/70)	1.0×10^{-5} 6.6×10^{-6}	2.4×10^{-6} 1.5×10^{-6}	1.2×10^{-5} 8.1×10^{-6} Total Risk - sum of handler and post-application risks for both products 2.0×10^{-5}
dip (4 gallons) (5/365)(40/70) and spray pump (dog) (one-half bottle) (5/365)(40/70)	1.0×10^{-5} 3.0×10^{-6}	2.4×10^{-6} 8.4×10^{-7}	1.2×10^{-5} 4.4×10^{-6}

			Total Risk - sum of handler and post-application risks for both products 1.6×10^{-5}
spray pump (dog) (one-half bottle) (5/365)(40/70) and powder (entire container) (5/365)(40/70)	6.6×10^{-6} 3.6×10^{-6}	1.5×10^{-6} 8.4×10^{-7}	8.1×10^{-6} 4.4×10^{-6}
			Total Risk - sum of handler and post-application risks for both products 1.2×10^{-5}
aerosol (Entire can) (5/365)(40/70) and collar (dog) (2/365)(40/70)	1.1×10^{-8} 3.8×10^{-10}	4.7×10^{-10} -----	1.1×10^{-8} 3.8×10^{-10}
			Total Risk - sum of handler and post-application risks for both products 1.1×10^{-8}

Conclusions

In Table 15 the aggregate residential risk varies from 1.6×10^{-5} to 1.1×10^{-8} . The risk is dependent on the product selected, the number of pets, the species - whether cats or dogs, the amount of product used, the number of days the product is used, and the number of years the product is used. HED does not have this information concerning the frequency or amounts of use, and therefore has made assumptions for these variables that seem reasonable. However, with the exception of the aerosol spray, these risk assessments are considered to be Tier I assessments

due to the use of the draft residential SOPs. The values selected for use in the residential SOPs were intended to not under-estimate exposure, that is, to provide to the extent possible a high-end assessment. For SOP 9.1.1, the assumption of 10 percent of active ingredient for liquids, powders, and pump sprays and 1 percent of active ingredient for collars applied to the pet are considered to be high-end assumptions. For SOP 9.2.1, the 20 percent of the application rate available as dislodgeable residues, and the 10 percent of the active ingredient transferred to the homeowner are considered to be high-end assumptions.

Note that the assessment for the aerosol spray is considered to be more realistic, since the assessment is performed using data from PHED. Unit exposures from the Pesticide Handlers Exposure Database are considered to be central tendency, that is, within the central portion of a distribution.

Considering that residential risks must be aggregated with the dietary (food source) carcinogenic risk, residential carcinogenic risks should generally be less than 1×10^{-6}. Most of these scenarios exceed this range. The assessment has been refined by the use of a dermal absorption factor. Additional information or other methods of estimating exposure will be necessary to refine these assessments.

For tetrachlorvinphos, the aggregate carcinogenic risk is a combination of residential and dietary exposure. The residential exposure is a combination of application and post-application risk. The dietary exposure is from food only; there is no dietary exposure through drinking water.

The previously estimated carcinogenic dietary risk for adult males is 7.7×10^{-7}.

Table 16: Aggregate Carcinogenic Risk - Food and Residential (Handler and Post-Application)

Scenario	Total Residential Risk[1]	Total Aggregate Risk[2]
dip (4 gallons) (12/365)(40/70)	3.1×10^{-5}	3.2×10^{-5}
aerosol can (entire can) (12/365)(40/70)	5.5×10^{-8}	8.3×10^{-7}
powder (entire container) (12/365)(40/70)	2.0×10^{-5}	2.1×10^{-5}
pump spray (dog) (one-half bottle) (12/365)(40/70)	6.3×10^{-6}	7.1×10^{-6}

dip (4 gallons) (5/365)(40/70) and powder (entire container) (5/365)(40/70)	2.0×10^{-5} Total	2.1×10^{-5}
dip (4 gallons) (5/365)(40/70) and spray pump (dog) (one-half bottle) (5/365)(40/70)	1.6×10^{-5} Total	1.7×10^{-5}
spray pump (dog) (one-half bottle) (5/365)(40/70) and powder (entire container) (5/365)(40/70)	1.2×10^{-5} Total	1.3×10^{-5}
aerosol (Entire can) (5/365)(40/70) and collar (dog) (2/365)(40/70)	1.1×10^{-8} Total	7.8×10^{-5}

1 Aggregate Residential Risk is from Table 15

2 Aggregate Carcinogenic Risk = Aggregate Residential Risk + Dietary (Food) Risk

5. FQPA Considerations

a. Cumulative Effects

Tetrachlorvinphos is an organophosphate.

Section 408(b)(2)(D)(v) of FQPA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common

mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also policies and methodologies for conducting cumulative risk assessments. For most pesticides, the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances. However, at this time the Agency does not have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. The Agency has begun a pilot process to study this issue further through the examination of particular classes of pesticides. Hopefully, the results of this pilot process will enable the Agency to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments. Exceptions include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case the metabolite must be assessed as part of a common mechanism assessment).

In making individual tolerance decisions, the Agency will determine whether:

1) it has sufficient information to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances;

2) it is unable to conclude that a pesticide does not share a common mechanism of toxicity with other substances; or

3) it is able to conclude that a pesticide does share a common mechanism of activity with other substances.

At this time the Agency has not yet made a final decision concerning a possible common mechanism of toxicity for the organophosphate class chemicals. The risk assessment has been performed for tetrachlorvinphos only assuming that no common mechanism of toxicity exists. However, these decisions will be reexamined after methodologies and procedures for integrating information concerning common mechanism of toxicity into risk assessments are developed by the Agency.

The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether tetrachlorvinphos shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for tetrachlorvinphos need to be modified or revoked.

b. Endocrine Disruptor Effects

The Agency is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency

is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1996) to implement this program. At that time, EPA may require testing of propachlor for endocrine disruptor effects.

c. Determination of Safety

FFDCA section 408(b)(2)(A)(I) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe". FFDCA section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and residential exposures, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..."

Determination of safety includes consideration of special sensitivity to children, potential cumulative effects with pesticides that have a common mode of toxicity and aggregate risks resulting from exposure to dietary residues, residues in drinking water, and residential sources.

The database for developmental and reproductive toxicity of tetrachlorvinphos is considered to be complete at this time. A developmental neurotoxicity study was not required. There is no unique or special sensitivity for pre- or post-natal exposure. Based on these three factors, the Agency has concluded that the results of these data did not raise concerns regarding the use of 100 as the uncertainty factor. An uncertainty factor of 100 will adequately protect infants and children.

The Agency has determined that consideration of a common mode of toxicity with other chemicals is not appropriate at this time.

The permanent tolerance reassessments for meat, milk, poultry, and eggs cannot be completed until new magnitude of the residue studies are received. Nature of the residue data (metabolism studies) were used to estimate anticipated residues for the dietary assessment, and to estimate time-limited tolerances for meat, milk, poultry and eggs.

There are residential uses of tetrachlorvinphs. The aggregate adult lifetime cancer risk assessment from exposure to tetrachlorvinphos in food and as a result of residential uses, result in aggregate risk that generally exceeds HED's level of concern. However, as previously stated the assumptions used in the residential exposure estimates were intended to provide to the extent possible a high-end assessment.